UNITED STATES

DEPARTMENT OF DEFENSE

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ARMED FORCES EPIDEMIOLOGICAL BOARD

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PHILLIPS SPACE CONFERENCE CENTER
BUILDING 201, 1750 KIRTLAND DRIVE
KIRTLAND AIR FORCE BASE
ALBUQUERQUE, NEW MEXICO 87117

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AND
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PRESIDING

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TUESDAY

FEBRUARY 18, 2003

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8:00 A.M.

A-G-E-N-D-A

Opening Remarks/Presentation	Dr. Steve Ostroff	4
	Col. Rick Riddle	5
Welcome	Col. Jeffrey Blanchette, Vice Commander, Air Force Safety Center	14
Air Force Safety Center Overview	Maj. Sullivan	18
Air Force Safety - Epidemiology/Research	Ltc. Bruce Copley	45
Air Force Safety - Life Sciences Overview	Ltc. Tom Luna	68
Discussion	All	81
BREAK		
Question to the Board Public Health Advisory Body DOD Deployment Health Research Center	Cdr. Megan Ryan	88
	Cdr. Russell	91
	Cdr. Megan Ryan	99
Question to the Board Public Health Advisory Body DOD Deployment Health Clinical Center	Ltc. Charles Engel	118
Discussion	All	141
Question to the Board Public Health Advisory Body Global Emerging Infections System	Col. Patrick Kelley	150
Discussion	All	168
Working Lunch (Board Members and Speakers) Philips Space Conference Center		
Ethics Training	Maj. Tom Serrano	176
Discussion	All	193

BREAK

Question to the Board QuantiFERON - TB's Application in the U.S. Military — Col. Jeff Gunzenhauser. 205

CDC comparisons of QIFN to TST — Dr. Jerry Mazurek 209

QuantiFERON - TB — Dr. Jim Rothel 230

Discussion — All 246

P-R-O-C-E-E-D-I-N-G-S

8:00 a.m.

DR. OSTROFF: Why don't we go ahead and get started. As I mentioned to many around the room who were at dinner last night as well as this morning, this will be somewhat of a meaningful variety of reasons, not the least of which is the weather problems on the east coast which has really been a challenge to keep the schedule on track.

Let me just say that the fact that so many of the board members were actually able to make it here is a real testament to the dedication of all of the members. It's been a busy, busy period despite the fact that we haven't met since last September.

Speaking for myself, and I'm sure speaking for Col. Riddle, we both really appreciate all of the tremendous hard work that's been done by all of the board members over the preceding six months helping the armed forces deal with a whole variety of subjects, some of which are quite critical for mission.

Let me also thank Col. Blanchette for the willingness of the good folks here in Albuquerque and Kirtland for their willingness to host us. We are not an easy group to accommodate. It's nice to have such gracious hosts.

I'll also mention that I have my usual winter respiratory infection so I'm going to try to minimize the amount of talking that I'm doing so I won't spend the whole day coughing. Once again, I'm going to let Col. Riddle handle most of the hard work. I'm going to turn it over to him.

COL RIDDLE: Well, good morning. I apologize. I think we are going to be able to make do. Hopefully we'll be able to find the meeting materials. We set up a kind of worldwide teleconference capability so people will be dialing in and out. I think we have been able to contact every speaker except one and will be able to do their presentations virtually with slides being presented here and the speakers over the teleconference.

Dr. Kilpatrick couldn't make it today so I will act as the designated federal officer for the board and call this meeting to order.

Col. Blanchette, Col. Cropper, the folks here at AFRL and the folks on base that have helped us have really been outstanding to put this thing together against all odds. I can plan for a lot of things but natural disasters is not one of those. We'll move forward.

Dr. Winkenwerder, Ms. Embrey, Lt. Gen.

Taylor, Brig. Gen. Ford, and Mr. Bowling ask that I pass along their regrets. They had planned on being at this meeting but at the last minute because of operational concerns, and the snow storm even on top of that, they had to send in their regrets. They certainly ask that you accept those regrets and wish us the best for a successful meeting to the Armed Forces Epidemiological Board.

I guess we should probably go around the table and have everybody introduce themselves. Dr. Herbold.

DVM. HERBOLD: John Herbold, University of Texas, School of Public Health.

DR. LEMASTERS: Grace Lemasters, Department of Environmental Health, University of Cincinnati.

DR. PATRICK: Kevin Patrick, San Diego State University, Graduate School of Public Health.

DR. POLAND: Greg Poland, Mayo Clinic, Rochester.

DR. SHANAHAN: Dennis Shanahan, Injury Analysis.

DR. ALEXANDER: Linda Alexander, Digene Corporation.

DR. CAMPBELL: Doug Campbell, Private Consultant and I've recently accepted the job as

branch head of the Occupational Environmental Epidemiology at the North Caroline Health Department.

COL. CROPPER: Leo Cropper, U.S. Air Force Research Laboratory.

DR. OSTROFF: Steven Ostroff from the National Center for Infectious Diseases at the Centers for Disease Control and Prevention.

COL. RIDDLE: Rick Riddle with the Office of the Secretary of Defense, Executive Secretary for the AFEB.

DR. BERG: Bill Berg, Hampton Health Department.

DR. GRAY: Greg Gray, University of Iowa, College of Public Health.

DR. GARDNER: Pierce Gardner, State University of New York at Stonybrook in the Fogarty International Center, NIH.

DR. FORSTER: Jean Forster, School of Public Health at the University of Minnesota.

DR. CLINE: Barney Cline, Tuland University, Department of Tropical Medicine.

DR. CATTANI: Jackie Cattani, College of Public Health at the University of South Florida and Center for Biological Defense.

COL. RIDDLE: The folks on the

teleconference, you want to go ahead and introduce yourselves? I'm sure folks will be calling in and out all day today and tomorrow.

DR. MALMUD: Leon Malmud, Temple University School of Medicine.

MS. RUNYAN: Carol Runyan, University of North Carolina, School of Public Health.

CAPT. SMITH: Jack Smith, Office of the Assistant Secretary of Defense Health Affairs.

CAPT. SCHOR: Capt. Ken Schor, Headquarters, Marine Corps.

MS. BENNETT: Severine Bennett, HS Federal Health Care working with Col. Riddle in the Office of the AFEB.

DR. OSTROFF: Anyone else on the line? Let me thank you for your willingness to participate remotely. We understand that you have to jump on and off the line over the course of the day. Please let us know if there are any problems picking up any of the discussion that's going on. Also feel free to contribute.

COL. RIDDLE: Let's see. We do have some presentations, but hopefully we will be able to locate those. We'll do that in the morning. I've got a couple of things here. Dr. Winkenwerder wanted me to

read a letter that he signed to the Board.

"Dear Dr. Ostroff. My sincerest gratitude to you and the members of the Armed Forces Epidemiological Board for your recent service to the Department of Defense and providing recommendations on the disposition of human remains resulting from the use of biological warfare agents.

This recommendation was briefed at the highest levels of the Department and accepted as a basis for our policy in dealing with this issue. The accomplishments of the AFEB are realized through the selfless dedication of each of the members of the board motivated by patriotism, good citizenship, and a sense of public responsibility to the health and welfare of the men and women of our armed forces.

The timely work of the Board over the holiday season developing this recommendation clearly exemplifies this unparalleled dedication. Over the 50-plus-year history of the AFEB the volunteer service of its members to the United States and to the Department of Defense has been unswerving, loyal, and essential to the medical readiness of the men and women of our armed forces.

The ability to seek timely independent scientific advice from a committee of noted experts

has, and will continue, to be essential to the Department's efforts to meet our national obligation to protect and conserve the health of military men and women for all future deployments and combat operations.

Please extend my most sincere appreciation to the entire Board for their exceptional work. With personal regards, William Winkenwerder, the Assistant Secretary of Defense for Health Affairs."

DR. OSTROFF: Yeah, and I'd like to also personally thank Greg for all of the work that went into putting that particular recommendation together, as well as Bob Schoff who seems to be more respiratory challenged than I am at this particular time and was unable to make it at the last minute because of illness. It was mostly through their work that we were able to put this together.

COL. RIDDLE: I have a few administrative remarks. I certainly want to thank Ms. Ward and Ms. Karen Bralley and Ms. Severine Bennett for all their efforts supporting the Board in preparations for this meeting.

Col. Blanchette, Col. Cropper, thank you for your support of the AFEB and assisting me with planning. In particular, Ms. Donna Alciver, the Base

Protocol Officer, Mr. Larry Hopkins, Ms. Marcine Hood, Lt. Col. Bruce Copley. Some of Bruce's staff here are actually helping us out, Bruce Burnham, and virtually making copies for us and then getting people on and off.

We have a couple of changes that you will note on the format for the agenda. One of those is that we'll have the executive session this afternoon. We may not have committee breakouts. We may stay in here but we have the capability to do breakouts if necessary. One of those issues is Dana Harkin wants to brief us this afternoon on the Iowa Army Ammunition Plan Health Study Protocol.

We also have a discussion this afternoon on the DOD smallpox vaccination program and the initial program report which I will distribute later on today. Importantly for this meeting, and thanks to the hard work and diligence of Karen and Severine, and support from the Uniform Services University of Health Sciences, we are able to offer 14.75 continuing medical education credits. To receive the credits you need to sign up on the physician roster that's out on the table.

Also I have evaluation sheets that you need to turn in. We were going to have the certificates

for you here tomorrow but what we'll do is we'll just take the names from the sign-in sheets. Also those on the teleconference and we'll prepare those certificates and mail those to you.

The next Board meeting is going to be on 20 and 21 May, 2003. This meeting will be co-hosted by the Armed Forces Medical Intelligence Center, United States Army Medical Research Institute for Infectious Diseases at Ft. Detrick, Maryland. We already had a full agenda and it should be a really good meeting.

DR. POLAND: Rick, could you repeat those dates? I'm sorry.

COL RIDDLE: Oh, the dates are 20 and 21 May, 2003, which is the third Tuesday and Wednesday of May. We'll send out -- we're going to try to get the invitations and preliminary information up on our website as quick as I get back in the next week or two.

There is also a sign-in roster out on the table so if folks would sign in both today and tomorrow. Refreshments are available for both morning and afternoon sessions and we'll have a working lunch here in the conference center. I think we'll have everybody invited that's attended here at the meeting. I think we have enchiladas today and fajitas

tomorrow. That will be good.

Restrooms are located just right out the door straight down the hallway to your left. There's a bank of telephones for feats copies, messages. Just see me or Lt. Col. Bruce Burnham or Bruce Copley. We'll have the meeting transcripts up on the website in a few weeks.

Also, we want to remind everybody that this is an open meeting and we do have some members of the press here. I actually think from the Chicago Tribune attending the meeting today. We'll have the handouts available. Hopefully we'll be able to find our notebooks, but otherwise we'll just do them in real time.

There has been a couple of changes to the agenda because of some rededication of forces down at CDC and the postponing of the CDC expert review on malaria chemoprophylaxis. We have actually moved that agenda item to May. We'll address two questions on malaria in May. One of them will be for primaquine prophylaxis and the other one will be overall recommendations for malaria chemoprophylaxis for DOD.

Because of operational priorities we've had a couple of folks that haven't been able to attend but I think we've been in touch with most everybody and

will have those presentations ready.

For dinner tonight we should meet over in the Kirtland Inn lobby at 6:20. We are going to have dinner at the Monte Vista fire station. That's open to all attendees and spouses. What we'll do is when we convene this afternoon we'll just do a show of hands so we can give the restaurant a call. I'm told that it's one of the top spots in Albuquerque and you will really enjoy your meal there. I hope everybody can attend with us.

I'll go ahead and do the introduction of the speakers and we'll save Dr. Ostroff's voice for discussion. Our first speaker this morning is Col. Jeffrey Blanchette who is the Vice Commander at Headquarters Air Force Safety Center.

Col. Blanchette.

COL. BLANCHETTE: Dr. Ostroff, Col. Riddle, thanks very much. Why is the Air Force Safety Center hosting an Armed Forces Epidemiology Board? At the board member's places there's a book called "Air Force Safety." We just completed a 10-year review of our database and identified areas that we as a service need to delve deeper.

But it started about five years ago when some of my predecessors recognized that we did not

have the expertise to really delve in to our database and find the causes -- the root causes and the things that we can do to reduce mishaps.

We searched around and being a military organization looked at what are the opportunities for us to gather additional expertise, at reasonable to no cost obviously, to help us investigate and delve into things that cause our people in the Air Force not to be available to do their jobs.

We paired and teamed with the medical profession because they have expertise in sorting populations, root causes, and things that need to be investigated to determine where can we devote resources to reduce incidents of not mission capable folks and people critical.

Lt. Col. Bruce Copley is the ramrod behind this effort from the Safety Center. Bruce Burnham, will you step inside? Lt. Col. Bruce Burnham, and CAPT Matt Shim are three very professional officers that we have working with the Safety Center helping all of the functional experts in delving through the database and making sense out of all of the information we have.

The other caveat that I want to place is about five years ago when I left the center the first

time it was recognized that as we bring people in, we have discovered that the data that we collect is incomplete. Now as part of our 10-year look back looking at other areas that data is collected, cross referenced to like-type events, but not necessarily shared in the analysis part of the process.

Now we're reaching out to the Air Force medical community to help correlate injury information and illness information that the medical community collects that sometimes does not get into the safety community. We are finding holes in the process.

Last September Bruce came to me and said, "Sir, I would like to propose that we host the Armed Forces Board." I recognized it and convinced our boss that it was important that we extend our partnership efforts a little bit further.

I'm very, very impressed that across the country everyone has the dedication to try to help define areas that we can work on to improve our ability to do our mission, the Air Force, and also to help the entire United States in prevention of disease.

General Hess would have liked to have been here today. If you've been paying attention to the news, you know he's part of the NASA Interagency Board

that's investigating Columbia. Today I think he's back in Houston.

We also have four or five other folks with him, as well as the other 10 members -- nine other members of the Board that are processing information and wreckage and data. On behalf of General Hess, welcome to the Albuquerque area here at the Phillips Lab Conference Center. You'll find some great folks willing to help you.

If you have not driven around Albuquerque before, one of my standard pitches is always expect the unexpected. People tend to drive around here like they're not sure where they're at or where they're going. When they are in the left lane and they come to the street and they want to turn right, they do across three lanes of traffic. Be prepared.

A red light is a caution. People either leave early or don't stop so be prepared for close calls. Normally we have sun. You are probably going to have a chance of experiencing rain showers. The only good news is it rained last week so the streets are a little bit cleaned off.

Otherwise, they are very, very slick because it just does not rain here very often. People don't slow down. Actually, they speed up, I think. It gets

a little dangerous on the roads. Please be careful out there.

If you haven't heard, you can always expect to have a drunk on the road around New Mexico and Albuquerque at any time of the day as proven by police reports and accidents.

Enjoy yourself. If you need anything as far as support administrative wise or how to get things done or get around down, Bruce Copley and Bruce Burnham, Matt Shim and a few of the other folks in the center are going to be in and out of here the entire time. Please, please ask for help. We are firm believers in showing you all a good time. Please enjoy yourselves.

DR. OSTROFF: Col. Blanchette, thank you very much for your comments. I think Col. Copley will now take over.

LTC COPLEY: Yeah, I'm a bit respiratory challenged myself. Instead of me giving the mission brief, Maj. Tig Sullivan, one of our line officers from the center, has graciously volunteered for me to save my voice.

DR. OSTROFF: It is that time of the year.

MAJ SULLIVAN: Is my speaker working? That big button, sir, on the front here? It says audio on.

Light is on. Hello, hello, hello.

DR. OSTROFF: Can I just ask can the people on the phone hear the presentation?

MS. ALCIVER: Yes.

MAJ SULLIVAN: All right. I'm Maj. Tig Sullivan. Good morning, Dr. Riddle, Dr. Ostroff, and ladies and gentlemen of the Board. It's an honor and a privilege to be here this morning to give this briefing. When Doc Copley asked if I could do this, I said, "Yes, I'll do it."

It's kind of exciting to get to talk to medical types because I'm an aviation guy. My only experience with medical types is the annual physical that the flight surgeon gives us. We all are in perfect health. I can see perfectly. I'm fine. I'm healthy. There's nothing wrong with me.

Also, when I first came in the service when I was about 18 years old there was an outbreak of -- how can I say it? -- crabs and scabies in the dorm so that's my only experience with epidemiology. That's about all I want. Every now and then when I think I've got a brain tumor or something I go talk to Doc Copley or Doc Burnham and they tell me all of these terrible bubonic plague stories. I'm like, "I'm feeling fine, Doc."

Anyway, this morning what I want to do is just give you a mission brief on the Air Force Safety Center. I would like to welcome you to Kirtland Air Force Base, home of the Air Force Safety Center. I'm just going to give you a quick overview pretty much of aviation and ground mishap rates, what we do at the Air Force Safety Center, what we're experts at, and kind of a vision of where we're going in the future.

Should I point it at that or the screen? There we go. Hazard identification risk management must be applied throughout the different systems to effectively eliminate mishaps. Our mission directly supports the United States Air Force overall goal of defending the United States, protect its interest through aerospace power.

That sounds pretty awesome, doesn't it? With all this big war stuff going on and just the talk of it, everybody thinks, "Safety? What does that have to do with aerospace power?" As you all know, if no one is alive to fight the war and no one is feeling well enough to fight the war, what good is it?

Over the last 50 years we've had a lot of neat things happen. First of all, the United States Air Force was born. We are regular like little kids compared to the Navy and the Marine Corps and the

Army. But in 1947 we became a service of our own.

Since that time we have collected data. All kinds of data on mishap rates, fatalities, and all that stuff that epidemiology loves to collect data on. I know that some of you have the Tome in front of you, the 10-year look back on our mishap rates. A lot of great data in there.

First thing I want to talk to you about is aviation. Am I pointing at the right place here? There we go. Aviation mishap rates. Okay. Well, is there a keyboard that I can just use the plus and minus key? There we go. It just takes awhile, I guess, for the slides.

You can see here since 1947 we had a nasty mishap rate, 44.2 in 1947. This is all figured out to 100,000 flying hours so this is all -- I forgot the correct term but it's all at the same rate level so it's all corrected to 100,000 flying hours.

What that says here in 1947 we had 44 mishaps per every 100,000 flying hours. That's a lot. You should see our fatality rate from 1947. Very, very high. You go down through here and you have 8.3 in the early '60s. Then most recently 1.5 mishaps per 100,000 flying hours. Considerably a lot better than we've been in the past but we still have a lot of room

to grow.

In the last 10 years you'll notice on your charts there that you have in front of you that the mishap rate stayed under 2, 1.5, 1.4, 1.1, things around that range. But our goal at the airport Safety Center is zero because we don't want to have any mishap rates whatsoever.

COL. BLANCHETTE: You might want to define what a Class A mishap is.

MAJ. SULLIVAN: Yes, sir. Glad to. A Class A mishap -- I'll read it to you real quick, I guess. A Class A mishap rate is anytime a million dollars in damage, a fatality, or destroyed aircraft. It kind of gives you a quick -- last year we had 35 Class A aviation mishaps last year in fiscal year 2002 to just kind of give you an idea of where we're at.

Now we're going to talk about ground. This is kind of a neat picture. Can anybody guess how this mishap happened? This is a car. This is an F-15. You would think the plane must have taxied right on top the car. This guy, to understand the whole story, was on his cell phone. He drove his car underneath that airplane. Pretty intense. That's the kind of mishaps we deal with here.

These are ground mishaps. You can see that

we've done considerably better over the last few years. In 1990 we had looks like 1,500 mishaps per 100,000 people. Just most recently we had 700 mishaps per 100,000 people. Now, you say that is considerable. That's almost half. Again, 700 is way too many and our goal is to get that down much, much lower.

I've given you a quick synopsis of aviation and ground. What I want to talk about now is what we are experts at. Our primary responsibilities include nuclear weapons, weapon system safety oversight throughout the Air Force.

We also analyze data, conduct studies to prevent future mishaps, our oversight and participation in the entire mishap investigation, reporting, and follow-up programs. Also establishing safety training and qualification criteria. We minister to the Air Force Occupational Health and Safety Program and develop instructions and standards for occupational safety.

Also, we maintain occupational illness, injury statistics, and reporting these statistics to the Department of Labor and other agencies. Although this list does not include everything we do, these primary responsibilities are reflected in our areas of

expertise.

You ask what are we experts at? Well, hopefully the next slide will help. The safety subject matter experts. I am just one of about a dozen pilots at the United States Air Force Safety Center. What we do is there is a group of us that are mishap investigators.

Anytime there is a Class A mishap in the United States Air Force, wherever it is throughout the world, they send one of us to go out to that mishap. What we are is we are kind of the consistent thread of mishap investigation. We are the guys that have been there, done that, got a t-shirt, and we are the ones that send people down the right avenue.

The other one with the mishap investigations, last year I say we did about 35 Class A mishaps. Now, when you think about the magnitude of that, each mishap is about 30 days long and they could be anywhere in the world including the areas of operation, Southwest Asia, Southeast Asia. It could be in Africa. We've had mishaps just about everywhere.

I haven't been around for one in Antarctica yet but one of these days we might have one there. The mishap investigation is we are kind of the hotbed

of knowledge for the United States Air Force and we share a lot of that knowledge with the Army and the Navy also.

Our safety policy. I work on the safety policy branch. We come up with all the information, all the regulations, all the instructions that have to do with Air Force safety policy. That includes AFI 91.204, 91.202. Some of the AFPDs that we have already talked about. Also some of the Air Force manuals we're coming up with.

Safety training. Did you have the chance to go out to the crash lab, or are you going to have a chance to go to the crash lab? Probably not. The Air Force crash lab is really a neat place to go. It's a bone yard of sorts of old Air Force crashes would it be helicopter or jet. We use that for training future Air Force investigators, flight safety officers, Aircraft Mishap Investigation course. Even the Board Presidents course.

What you do is you go out there and you see all these crashes and you try to figure out why did this plane crash. It's a great learning tool. We have all kinds of safety training right here at Kirtland.

Also Col. Blanchette mentioned earlier the

data collection and storage analysis. If you get a chance to go to the Air Force Safety Center you'll see that we have a whole branch of just data collection people. We have this capability of collecting data and storing it for long periods of time so we can analyze it. Doc Copley and Doc Burnham are kind of the masters of how do you tap into that data and pull all that information out.

The organization is pretty simple. You have Maj. Gen. Hess up here at the top. He currently, just to kind of give you the magnitude of what we do here, is on the Space Shuttle Columbia mishap investigation board. He is, I believe, in Houston, Texas right now along with ADM Turkot from the Navy and a myriad of other people and experts.

He holds two offices. He has one at the Pentagon along with this Issues Division of about half a dozen people. Primarily the rest of us are here at Kirtland Air Force Base. He holds the position as a Commander of the Air Force Safety Center. Then you have the Vice Commander Col. Blanchette down here. We have Col. Clark is the JA, the legal guy.

Then we have an executive staff of about three or four people. Then there's a whole bunch of us, I believe about 120 of us, through the Safety

Center to include a whole handful of engineers and civilians. It's about 50/50 give or take on civilian and military at the Air Force Safety Center.

The one that particularly appeals to me, obviously, is the aviation aspect. Again, there's about 20 of us in the aviation division to include all the pilots and also Doc Luna. I see him in the back there. I've got to mention him because he's a flight surgeon and my physical is due next month so I want to kind of make sure that he knows that I appreciate him being there.

What we want to do at the Air Force Safety Center is we want to build a culture that achieves world class safety performance. What has happened over the last 50 years we've gone through different transitions. Anyone who has been in the military with every change of the chief of staff or leadership, there always seems to be kind of change in philosophy.

Fortunately in the last four or five years that change in philosophy hasn't changed too much. It's very focused on risk management. How do we prevent these mishaps from ever happening again whether they are in the aviation world or in the ground world. How are we going to do that?

Well, our strategic objectives are pretty

simple. I don't want to just read them off to you but I think they are really important. We will continue our efforts to identify and eliminate hazards that continually reduce mishap rates.

We must use the Air Force planning program and budgeting system to secure resources for mishap prevention and risk management programs. Also we must improve career development with professional training and education of flight, ground, and weapon safety disciplines.

That has become very important recently because what has happened is we have all this great knowledge that at the Air Force Safety Center, and also the Navy and the Army too, but we have no way or no means of keeping that knowledge and keeping them there and training them to be better. Also enhance our outreach efforts to Air Force safety and other safety communities.

This includes strengthening our partnerships with commercial industry, internal organizations, our sister DOD services, and other federal agencies. We are currently engaged in several programs to achieve our strategic objectives. I know you are on needles and pins asking what are those?

Here we go. Operational risk management.

This is probably the foot stomper at the Air Force Safety Center right now. If any safety officer in the United States Air Force asks you anything, you can say, "Tell me about your ORM program or your risk management program."

He better have a real good idea what you're talking about because risk management is where we're at right now. We are trying to identify the hazards before they happen and eliminate, or at least mitigate those hazards before they ever happen so we don't have guys driving their cars under F-15s. That's what we're trying to do.

Also weapon site planning. That is another one of those foot stomper programs. We have one story in the AOR that happened about a decade ago, about 1991, where we did more destruction to our own equipment because our weapon site planning was so poor. A HUMVEE caught on fire and started to burn, which things do happen.

Unfortunately, the vehicles were so packed together and so close together that it caused this vehicle to catch on fire and this vehicle to catch on fire and this vehicle. Then this exploded and this exploded. We wiped out like 10 acres of equipment with just one minor mistake and it's all because of

poor weapon site planning. We did more damage to ourselves than any Iraqi force ever thought of doing.

The other is mishap analysis animation facility. That's probably the leading edge of, "Gee whiz. Wow. That's really cool," technical stuff. That's the facility that anytime you look at CNN or MSNBC and you see the three-dimensional picture of how did the plane crash and the gauges and all that, that's what they do at the MAAF. They have like three engineers that work down there and they are very, very good at taking data and making it into a viable picture.

Another way we're doing it is through MFOQA. That's kind of a hard word to say, MFOQA. What it started off with is in the AMC aircraft and it's the C-17 right now today. What it is is taking information inside the cockpit and being able to pull it out and train people outside the cockpit with the information inside the cockpit. It's a continual process. In the near future ideally we want it in all the AMC and expand it out even to all the other airplanes also.

Traffic safety. This is probably -- not probably. This is the one area we are the weakest at. We lose more airmen every year than we do in the five

or six years of aviation mishaps. When a plane crashes everybody in the Air Force stops and we all breath and we go, "How are we going to do this?"

When there's a car crash, when an 18-year-old kills himself in a car or 20-year-old kills himself on a motorcycle, we just kind of go, "Well, that's a shame." Unfortunately, this is where we are losing the most people is in traffic.

I don't know how it is throughout the rest of the services but I'm pretty sure throughout the world that's where we're losing the bulk of our people and that's where we really need to focus a lot more of our information, a lot more of our training. A lot more of our attention needs to be on traffic safety.

Also, information technology investments. Col. Hess, Col. Blanchette, and a lot of the leadership is very big into let's get into the 21st century. When I first became a safety officer as a young captain about a decade ago, it was all pen and paper and we had a program called -- I forgot what it was called now -- Safety Program. It was terrible. It was like based on a 286 computer.

Now we are coming into the future and we are learning a lot more about how this data like the data you have in front of you we can use that data,

identify the problems we want to go to, and then focus like a laser on those problems and try to eliminate the problems in the future. The only way we can do that is we have the capability to gather all that information.

I can go backwards but I can't go forward. There we go. I talked a little bit about this. This is just a quick slide on our integrating risk management in the future. We have our traditional way and in the future how we are going to do it. We have to be proactive.

We have to evaluate the risk, focus on the mission. This is the key. Everyone has to be involved in it. That's the only way we can do it is if the youngest guy, the 18-year-old guy that drives his motorcycle at 110 miles an hour down the interstate, he has to be the one that has to go, "This isn't a safe program. I better slow down and start paying attention."

The other way is through leadership. This is the real key for most all of us in this room. We have to hold people accountable. We have to drive the culture through out leadership, articulate the vision and values. Also in the future we're going to have to invest a lot more in safety.

To conclude our briefing this morning, I just want to give you a quick picture of our website. If you don't have the opportunity to get on our website while you're here, when you get back go ahead and hop onto it. It's real easy, safety.kirtland.af.mil. Tons of information. Tons of data. Tons of information that can help you out in the future.

I've talked briefly about the Air Force safety mission, about what we do and where we're going, what we're experts at, and how we are going to get there. My name is Maj. Tig Sullivan and I appreciate your time. I appreciate the Board's indulgence on our small computer problems and my lack of good verbal communication. I appreciate your time. Thank you very much.

DR. OSTROFF: Maj. Sullivan, thank you very much. Let me open it up to the Board if they have any questions. I have a couple if you don't mind.

MAJ. SULLIVAN: Not at all, sir.

DR. OSTROFF: I don't know if you are going to discuss some of the data that are in the pamphlet or whether or not that will be in the next presentation, but I'm curious about why there is such divergence between Class A, Class B, and Class C in

terms of what's been happening over the last 10 years.

The other question that I had is is there a similar organizational unit in the other services and do you share information across the other services?

MAJ. SULLIVAN: To answer your last question first, yes, the Army and the Navy -- the Navy Safety Center in Norfolk and then the Army Safety Center down at Fort Rucker. We communicate quite a bit through different means whether through joint senior service -- the JSSC where all the leadership from those branches get together and talk about safety issues.

But also individually like myself and other guys at the Safety Center we have other ways of communicating with those guys personally. We've met through meetings and things like that. We do communicate. We are trying to improve that quite a bit, though, because the Navy has learned a lot of stuff that we need to learn and we've learned a lot of stuff the Navy and the Army need to learn also.

The first question was you asked about why the divergence between A, B, and C. Are you talking about aviation or ground?

DR. OSTROFF: I think it's total. It's the very first set of graphs that are in the brochure. There is a comment at the end of the brochure that

says it's due to better reporting in B.

MAJ. SULLIVAN: Right, sir. That was, if you'll notice, Class B you see the spike about four or five years ago.

DR. OSTROFF: Right.

MAJ. SULLIVAN: I think that was 1999. There is a lot of theory and philosophy behind that but one of the philosophies behind it is about that time is when people start becoming a lot more paying attention to Class B mishaps and the reporting became a little more easier and a little more -- the leadership said, "Hey, we need to report this up. We need to report this up."

That's part of the philosophy. Also there was some dollar changes that changed that year also. Something that might have been a Class C 10 years ago might be a Class B starting in 1999.

LTC. COPLEY: Excuse me. This is a classic surveillance situation where the data are sort of a figment of how we change things administratively. For instance, in Class B we have something called foreign object damage. Pilots are used to this where you suck something into the engine. Those are always classified as Class X until about '99 or 2000.

Then we started classifying them according

to the dollar value so they became Class B. It's just like changing any case definition in surveillance. We run into the same problems that public health agencies run into. Out data looks kind of weird sometimes and it can be explained away by what we do as far as setting the rules.

DR. POLAND: I have two questions. The first is the Class A mishap rates by duty status are actually the inverse of what I would have expected unless I'm missing something.

MAJ. SULLIVAN: Are you referring to --

DR. POLAND: Why would not only this year but the 10-year mishap rate be lower for the reserve troops as opposed to the guard as opposed to active duty? I'm assuming this is normalized for flight hours.

MAJ. SULLIVAN: It is, sir. Everything has been normalized for 100,000.

DR. POLAND: Isn't that, at least on the surface, surprising?

MAJ. SULLIVAN: You would think that the reserve and guard would be higher or lower?

DR. POLAND: Higher.

MAJ. SULLIVAN: Well, first of all, they are working with much smaller numbers. We have like 2

million flying hours in active duty and the reserve and guard, if I recall correctly, was in the hundreds of thousands.

DR. POLAND: Again, isn't this data adjusted for that?

MAJ. SULLIVAN: Yes, sir, but, if I recall correctly, just using last year there were four mishaps in the reserve or guard and it kind of spikes up when it's normalized. I guess I don't understand your question I guess.

DR. POLAND: Well, it would seem that somebody who flies 10 times the number of hours of somebody else, yes, I guess the potential is greater for an incident but they would also have more experience.

COL. BLANCHETTE: Let me address it kind of indirectly. If you do a population study in the guard and reserve, you will find that on average guard and reserve air crew members have significantly more experience flying the specific air frame that they are flying.

So from an experience background you have people that have been exposed to the circumstances and potentially have a better ability to handle emergency situations.

On the ground support side of the house, the maintenance, you will find similar parallels in that we take people from our active duty forces that depart active duty and try to hire them into the reserve and guard so we will gain a person in the guard and reserve that may have five to 10 years of active duty experience before they come into the work force. On the Air Force side of the -- on the active duty side of the house we are taking a young high school graduate off the street giving him about 90 days of training and putting him out on the flight line and saying, "Make sure this airplane is flyable." You have to understand the population differences, too.

DR. POLAND: Okay. That's a fair answer. My second question is do you have this data by things like age or time of day, factors that you potentially could work around or do something about?

MAJ. SULLIVAN: Yes, sir. The book in front of you we call the Tome. We just did it in major categories. We could break it down even to smaller details like that maybe like on the traffic mishaps. We've done that with time of day like night and day, things like that. With aviation we could break it down to night vision goggles, night time, day time but we didn't do it with that information but we do have

that capability of breaking it down even further.

Yes, sir.

DR. CAMPBELL: I have a question on one of your earlier slides where you showed the rate being really high for Class A in the 1950s.

MAJ. SULLIVAN: Yes, sir.

DR. CAMPBELL: And then through the '60s and '70s it dropped pretty consistently down even though the Vietnam War years. Why do you think that progressive decline happened even with such a big conflict.

MAJ. SULLIVAN: There's a lot of theories but one of the biggest theories that I'm a proponent of is system safety. Back in the late '40s, early '50s, '60s the whole idea of building an airplane was built.

We would buy 4,000 F-100 airplanes and the system safety that was built into it wasn't as great as buying an F-22 where things have been thought out mechanically, electronically, all these different systems where they built in at the most basic component huge amounts of system safety.

We are going to build this pump to have a safety factor of 1.5. They build a pump which puts in a wing which goes into the landing gear which goes on

the base of the airplane. You have this airplane from the ground up has been designed to be safe.

Whereas 50 years ago that philosophy wasn't totally there. The philosophy was let's just build this airplane, make it as safe as possible, but that's good enough to go. I think that contributes to that first 30 years of just huge decreases in safety -- mishaps. Excuse me.

DR. CAMPBELL: Two questions. Did the culture change? Did people fly their planes differently or act differently, No. 1. And how did human factors enter into the change in the numbers?

MAJ. SULLIVAN: Doc Luna is the expert on human factors but I think it goes hand in hand. You have system safety, but also you have an attention getting device. People saw that 2,000 of their aviation brothers and sisters were dying and it became more of a, "Hey, you know, this doesn't make sense. Why are we doing this?" The leadership started saying, "Hey, if it's not safe, don't do it."

I think there was a human factor involvement in there without a doubt. But, you know, that human factor is relatively new. I say relatively new as far as, you know, ingraining it in people as their second lieutenants in aviation training. Let's start off

here with day one and teach them and train them about the human factor issue.

Whereas 40 or 50 years ago I don't think that was there. I think it was more seen as pants flying, more, "Hey, I can do this." Chuck Yeager, you know, The Right Stuff. "I'll fly this plane until it can't fly anymore." That kind of mentality. I think the philosophy has changed over the decades.

DR. PATRICK: On page 32 there's a very interesting graph that shows this divergence of on-duty and off-duty ground mishaps which suggest a real opportunity for community level assessments and interventions. What are you looking at there? How are you engaging your community partners, the places where these folks live and work?

MAJ. SULLIVAN: Sir, you know, that is Maj. Gen. Hess' probably favorite chart. You can thank Dr. Copley for coming up with that chart. That is something that really got his attention and the Chief of Staff of the Air Force attention is that chart you're looking at. It's because all of a sudden we live in a world of the X games and this is our theory right now, or using a hypothesis right now.

In the last two, three, four years what kind of young men and women are coming in the military?

When I came in the military when I was 18 years I did things totally different than what an 18-year-old does right now.

It is nothing for an 18-year-old to obey the rules, come in the military, be the best troop, best airman, do everything great when he's at work from 7:30 to 4:30. But there's something that happens. Our thinking is something happens from 4:30 until the time they go to bed at night. What it is they have grown up with the X games mentality.

You've seen TV, the ESPN 2 stuff where, "Good Lord, how did they do that?" They are skateboarding off of roofs of houses. We have videos of guys on bicycles being pulled behind a van onto a ramp to try to jump over a two-story building. Who thinks of this stuff?

What's so worse about it is there's 50 people watching him do it and not one of them is going, "Jim, this is the stupidest idea I've ever heard you come up with." Our thinking of what's happening is this generation, this last two, three, four years coming in the military is they get off of work, they put on their X game helmets and say, "Let's go."

Now all of a sudden they have $15,000,

$20,000 a year to go buy a crotch rocket motorcycle. They go down the highway at 120 miles an hour and it seems perfectly safe to them. Whereas us when we were 18, 19 years old that just terrified us. What we're doing in the future is we're trying to identify those groups and that group is for us in the military 18 to 25.

That's where our high-risk group is. That's where people are dying and that's where people are getting injured. We are trying to focus like a laser beam, per se, on those groups and get their attention and say, "You've got to get rid of this X game mentality. You've got to not only be safe at work but you have to be safe off duty." A lot of that comes from a leadership aspect, sir. In the military when I came in at 18 years old my boss was my boss.

I'm sorry, sir?

DR. PATRICK: I want to follow up. I tend to agree with a lot of what you're saying. It seems like there are also other factors in the community that might be looked at. I come from San Diego and I, too, really am saddened when I read in the newspaper of a 19-year-old recruit who has been killed on a motorcycle that they just bought the day before.

MAJ. SULLIVAN: Yes, sir.

DR. PATRICK: One of the things that's mentioned in here is skill or ability factors on these two-wheeled vehicles. It seems that looking at policies with respect to how people are able to purchase these things and working with local merchants and educational programs, there are a lot more questions than answers.

MAJ. SULLIVAN: Yes, sir.

DR. PATRICK: I'm not the expert in this area but it really seems we have others more expert in injury on the phone. I think Carol Runyan is on here. It really seems one will need to get into the community in which these folks are also spending their time and trying to address the factors that also influence them separate from the sort of risk mentality that you are describing, which is probably pretty important.

MAJ. SULLIVAN: Absolutely.

DR. PATRICK: Researchable questions here that I think are really very important.

DR. OSTROFF: Let's take one more than more on so we can keep on schedule.

DR. FORSTER: Does the Air Force Safety Center have responsibility for dependant's safety as well or just the enlisted -- the military people

themselves?

MAJ. SULLIVAN: Loose sitters and civilian GS types. If you're in the military, that's what we're responsible for.

DR. FORSTER: So families?

MAJ. SULLIVAN: Families we try but we have no, if you want to say, jurisdiction or holdover per se. More or less, if someone's spouse dies off duty in a car accident, we don't keep that data, ma'am.

DR. OSTROFF: Thanks once again.

Col. Copley, are you going to do the next one?

LTC. COPLEY: Yes, I will. Thank you, Maj. Sullivan.

Just a couple more thoughts on what Maj. Sullivan said with regard to that divergence. We do think that physical divergence actually represents a cultural divergence as well where there is a more clear separation between on-duty and off-duty life.

As he mentioned, that has generated hundreds of hypothesis. We re just now in the mode of trying to test a few and to try to lay out some more sound theories. We do think it's a cultural phenomenon so we are looking to address that. However, we will show you here our ability to capture all data points is

constrained like it would be in any surveillance system.

So I will go until I get the yellow light from Dr. Riddle, at which point I'll turn over to Dr. Luna for the human factors part. Let me proceed and I'll go as far as I can and if there is stuff you see on your handouts that you would like for me to go into detail on that we missed today because I will probably cut off early, I can always brief you separately off line anytime while you're in Albuquerque so please let me know.

I have the same technical nonsophistication here. Is it page up or page down?

MAJ. SULLIVAN: I was just using the arrow key, sir.

LTC. COPLEY: Okay. Page up?

MAJ. SULLIVAN: Down.

LTC. COPLEY: First of all we'll talk about some of the history of the Epidemiology and Research Branch where I work. What we do, some data and surveillance issues that drive the program, drive the data and drive what answers we can derive from the data. We'll look at some of the recent products we've done in the past 10 to 12 months.

To give you a little bit of history, the

history is going to be brief because our existence here has been brief. Back several years ago this Board, different people primarily, made the recommendation that the partnership between the Safety Centers and the Surgeon General increase and strengthen.

Sorry Bruce Jones isn't here to elaborate further. Maybe he will by phone tomorrow. This came to the report to the AFEB in 1996. That precipitated a whole lot of recommendations and a lot of activity. Also what it did precipitate was a visit from the AFEB team, a special team to the Safety Center here in Albuquerque.

It came in '97 where we at the Office of Prevention and Health Services Assessment were tasked to provide assistance to the Safety Center as a result of this report to the AFEB that generated enthusiasm for injury epidemiology and prevention.

So then we at OPHSA contracted with AFEB members at the time and Col. Vicky Fogelman, some of you may know Vicky, she was the AFEB executive secretary at the time and she recruited a team from the AFEB and the consultants to come with us to Kirtland. We came out here in '97.

You see a lot of these names here are pretty

familiar. They are still around today, still practicing public health and epidemiology. The ranks have increased fortunately. Here was the team that came out here and came out with these recommendations basically to concentrate -- we'll talk about Class C in a second but that is the higher frequency, lower severity, the more common place mishaps and injuries -- to continue to concentrate on collecting that data because those injuries that you see more of and are really critical for prevention.

Also, of course, to continue to collect the big stuff, the Class A and Class B, albeit they are sentinel events but they are lower frequency. Also to modernize the electronic reporting system. We have done that, too, to make reporting easier out in the field. Also to provide more analytical feedback to the field, and that's surveillance dissemination feedback mechanism.

A lot of data were collected. Very few data were going out as far as the summation of the data. Also, to partner with the Office of Prevention and Health Service Assessment in the Air Force for further analytical work. All of these things have transpired, as well as the last one here.

They have requested the Safety Center to at

least consider the prospect of hiring medical epidemilogists to come to the Safety Center and to analyze some of the data and get some of the mishap prevention information back out.

Our response to this whole thing was we hired in '97 the first epidemiologists followed by the second one just two years later. Lo and behold we got another one two years after that. We think we probably topped out as far as how many epidemiologists that the Air Force medical service can actually not lose but provide to the Safety Center as we are a non medical unit. We probably topped out there. And also they have added another requirement that one position be a doctorate, preferably Ph.D.

Here is the way we are laid out. We are a very small branch and we are made up of epidemiologists and psychologists as far as the professional part of the branch. We do have data analysts.

We have report intakers, people that bring the data in from the field. They look at it and they validate the reports. They clean the data up and they put the data in a mishap database. We cover both ground and weapons and flight, really three different functional areas.

So what is our role here at the Safety Center? Well, the traditional role of public health model of injury prevention. You've all seen this before. This is no strange stuff to anybody in this room. What we lack, not just at the Air Force Safety Center, but within DOD injury prevention is that we on the medical side the implementation part that you saw is a missing link.

Those programs are line. Supervisors and commanders, that's their program. It's not a medical program so we can't drive the system to do things the medical way, the way we would like to see the world. It's the line and supervisor world. We on the medical side at the center, or anywhere else in this sort of an arrangement, cannot really implement things unilaterally, which means just from a medical perspective because we want things done this way.

So that becomes really a big challenge. It's not an unsurmountable challenge but it is something that we normally don't see so much of in the medical world where you own the entire process in the public health model.

I'll talk about some data and surveillance issues now. Here's the scope of our surveillance system and our data. It's accidental death, injury,

occupational illness, and property damage. I emphasize the limitation here is accidental. We have a lot of things that we don't do.

Injury as defined by the DOD instruction 6055.7 is very narrow as you can see. This is not precise enough to really dictate a lot of precision. A lot of people miss -- you don't see heat injury. It is sort of implied but because you don't see heat injuries, many times are surveillance for heat injuries is quite weak. This is the DOD instruction. We merely mimic that in Air Force policy. We can't make our own rules here.

Also, the weaknesses here are the many exclusions I've alluded to. We leave out suicide, homicide, work place violence, legal intervention types of injuries. We also do not pick up combat related injuries because combat comes under a different reporting system, the casualty reporting system. We don't want duplicate kind of reporting so we don't play in that arena.

Also we don't do any surveillance on non-Air Force units. The mishaps, the injuries that we are concerned with by regulation are those that affect the operational Air Force. If you're wearing a blue suit like I am but you're assigned to a joint or unified

command or DOD agency like Col. Riddle, if you have a mishap despite the fact you're wearing a blue suit, you don't show up in the data.

Those are obviously not rules that we set locally or even the Air Force sets. These are handed down to us from upon high. Those are the rules of engagement. You have to realize what we're working with to realize what we can't do.

We've heard about these mishap categories, Class A, Class B, Class C. That's a foreign concept on the medical side, I know. It takes some getting used to. It's a convenient classification system for mishaps. We have other classes but these are our primary reportable categories.

It's based upon cost, based upon the severity of the injury. And also, sort of a function of cost, but you lose an aircraft, regardless of how cheap that aircraft was, which that's a misnomer. A cheap aircraft? I don't think so. If one goes down, that's a Class A.

Our Class B side, again, the cost is somewhat less. It can be a partial disabling injury, a permanent disabling injury, and three or more people are hospitalized. That constitutes Class B. Class C even more money and the severity level goes lower.

This is the threshold for reporting.

When we talk about lost workday injuries, which is a big thing in the military now, this is the threshold that they have met. They have lost at least eight hours beyond the current duty date, or an occupational illness of any duration. Those are our mishap classification systems and that's how they report through our reporting system that we'll talk about in a moment.

We have to realize, again, we're dealing with different case definitions. There is the injury part or the safety part, and there's the medical part. Two different definitions. The medical definition we commonly see governed by ICD-9 coding, etc. Ours come out to be like this: 165 fatalities, 105 of which are accidental or unintentional injuries; disabilities; this is hospitalized if you can't read it; treated and ambulatory.

Here you see the ratios, 1 to 3 to 5 to 1,100. If you only look at unintentional injuries, which this is the unintentional, most of these are unintentional. I didn't tease them out because it's too difficult for quick viewing but most of these are unintentional so you get a ratio of 1 to 4 to 9. Really important because the next slide will show that

this is very valid. The ratio of fatalities to hospitalized injuries 1 to 9.

This is using the definition that, again, we define medically. Defense Medical Surveillance System has an operational definition ICD-9 codes that we use for this particular slide.

Now, on the safety side we have different definitions governed by DOD instruction. You saw the limitations on that definition. But using that, you see that the ratio of fatal and disabling combined, the hospitalized is 1 to about 10. No matter which way you look at it, from a medical case definition or safety definition, we hospitalize 10 people for every one that we kill or permanently disable.

That's our ratio and it's kind of important to know what we're dealing with from this pyramid to know the burden of injury and where the severity levels fall and what those burdens are within those different levels.

You see right here it says hospitalized but not reported. If I say not reported, many of these, if not most of these, are not reportable under that DODI and Air Force instruction because they didn't want to lose a duty day. They would be hospitalized on a Friday and come back to work by Monday morning in

a cast sorting mail, no lost duty time.

There are loop holes in this case definition from the safety side. But, still, regardless of medical or safety definitions we see that 1 to 10 ratio stand up so that must be a very robust measure. That's how our burden of injuries look by their severity level.

Let's talk a bit more about surveillance. We use a system called the Air Force Safety Automated System (AFSAA). That is our web-based worldwide network for reporting. We run our operation very similar to the medical side where we have worldwide reporting. We are the hub. We have spunks going out to all the base safety offices. They actually report the mishaps.

Aviation, ground weapons, occupational illness, modules within SAS. The occupational health module is something new. It's a prototype and it's currently being appended, or added to, the Air Force's Command Core System which is a very comprehensive system for managing occupational health. It's a big initiative within the Air Force only right now. What we are aiming to do here is combine both occupational illnesses and occupational injuries into the same data stream for once.

Right now occupational illnesses go to Dr. Grayson's shop at AFIERA. The injuries come here and we have fragmented reporting from the occupational arena. Our merger here will have a single data stream and AFIERA, Kevin Grayson's shop, they can have access to the data, too.

For the official reporting we are the official liaison with the Department of Labor. We need good current figures so one data stream will make this much easier. And improvements in the software system will make the data that come in more clean.

Right now we have a dirty data problem and it's not Dr. Grayson's fault. It's just a function of the reporting system that is being revised currently. We are actively engaged in this prototype and actually inserting that prototype that we have perfected hopefully here into Command Core.

All the data gets put into this big database and the Chief of Staff of the Air Force and the senior leadership and click on the desktop icon. This is updated hourly as the reports come in. This is 4:12 on the 3rd of February about two weeks ago. This was a screen shot that we captured. It shows up to the hour how we are doing. This is the civilian occupational injury and illness combined rate.

This is the military down here. Hitting these hyperlinks users can drill down and actually see some details, a paragraph or two narrative of actually what happened in these particular mishaps. So senior leadership can be apprized of the situation right up to the hour and see what actually happened wherever.

Now, another key thing that we are tying to do here is to link up with Defense Medical Surveillance System and its data. What we aim to do here is to enhance our surveillance. Yes, our surveillance system is deep. We have mishap prevention information. It's highly specific, not very sensitive from a definition.

We are trying to increase the sensitivity. To do this what we aim to do is to basically use DMSS data to produce this right here. This has historically been a function of base safety. Base safety has walked over for years or decades to the base hospital and said, "Okay. Let me see your A&D sheet, your ER logs."

They investigate those that appear on those logs. With the proliferation of medical care outside the MTF mainstream, they can't just walk over to the base clinic or hospital -- if there even is one now. Many places don't have one -- and get these reports.

What we are doing is making limited medical data. Basically there are alerts or notifications that, "Hey, Safety Office, an injury occurred, was hospitalized last nigh (or whenever). You might want to investigate this."

We are trying to activate our surveillance system to rely less upon the passive mode so these things will go out in a secure link to the secure websites that only those bases that have those cases available to see that. That will alert them that injury has occurred and they can go out and investigate that.

Again, supervisors and commanders are supposed to support. Like with any surveillance system if you rely strictly upon the passive mode, you end up with significant under-reporting problem. We aim to kind of close that gap.

Okay. We signed the memorandum of agreement with DMSS, Army Medical Surveillance Activity, and we received our first download of these data on 13 Feb. and we are processing that now for distribution out to the field. So with no concern the medical data will be scrubbed and there won't be confidential information or any of that kind of problem out there. It will strictly be a notification that this person

was injured on a specific date and leave it at that.

A little bit about our research activity. We will probably only get to about the first half a dozen slides. We do a lot of different types of research. Operational research, why planes crash, etc. We do epidemiological research and also behavioral and human factor research. And we cover both flight and ground, and even we get down to the weapons category. Not much data there but we will work with any data set we can get.

Here are just some quick examples of some of the things we have done in the past eight to 12 months. We looked at motor vehicle crashes, Class A, for an extended period of time to look at initiators and contributing factors.

Dr. Riddle, do I need to step down now? I see the red light is on.

COL. RIDDLE: If you want to finish up real quick.

LTC. COPLEY: Okay. Let me get through this at least to show you what we found. Driving behaviors. What initiated the mishap? What was the first thing in the causal sequence? Why we wanted to know this was so we can tailor our driver's training on our Air Force bases, right now sort of the shotgun

approach. We want to tailor it a little bit to get more precise as to what we train people on.

The top one, these are automobiles and in the red are the same things we looked at for motorcycles. We always sort of lumped everything together like, well, what happens in cars happens in motorcycles. We found that there are some differences in those driving behaviors and those initiators.

In at least two of these there were significant differences between the driving behaviors of motorcyclist versus automobile drivers. This is what initiates the biggest part of our mishaps.

You see speed. That's a no brainer. We knew that was happening. We went ahead and said what would be contributors to these initiators and we looked at several contributing factors. We narrowed them down to the top five for this chart.

We see that, again, alcohol in our airmen continues to be a plague upon our planet, planet Air Force. Probably planet DOD. You see they differ by whether they are driving automobiles. These are just vehicle operators now. Or whether they are driving motorcycles. You see that alcohol regardless of what they are driving seems to be a problem.

For automobiles where there is a secondary

problem, not so much in motorcycles maybe because of foul weather and they don't drive on those days. That's the only rationale we have to explain that.

Also, on the motorcycle side we see regulatory compliance, an euphemism for basically they don't have the required Air Force training, or they don't have a valid state-issued driver's license or operator's license to operate a motorcycle. And so we see that training is a big issue.

And so fatigue, we thought we would see more of this. Again, our data are limited. We don't have all the information in the world. But even then with limited data, fatigue stands out as one of the top five contributing factors in our Class A, fatal and permanently disabling automobile and motorcycle mishaps.

Dr. Riddle, let me go through this really quickly. It will take me about five minutes. I think this will be really important. It's a very topical question that we've been getting about what about all this stuff that we're doing. We're driving people crazy with deployments. they are all over the planet. We are working people hard. Our mishap rates are being driven by this operational tempo.

We have a nice classification. Our manpower

folks in the Pentagon have actually done us a big favor by looking at their occupational categories and determining scientifically and objectively which ones are manpower stressed. The definition is very complicated. Algorithm is very robust so this is not a subjective feel at all. Very objective here.

We created this manpower stress category and it's dominated by security forces, about 22,000. They represent probably -- I've got it down here -- 70 percent of these manpower stressed Air Force career fields. On the other hand we have the non-stressed which is everybody else dominated by the big ones, mechanics of all types, maintenance people, information managers.

Here is the way the data played out to be real quick. Here is the raw data. What we are going to do, again, this is looking at operational tempo, manpower stress. What we are going to do here is divide this time line up into fiscal year 2000 and fiscal year 2001. Except for 19 days in 2001 all this is pre-9/11 because our fiscal year ends on 30 September so we have nice convenient periods where this is a pre-9/11 period. This is a post-9/11 period.

What we are going to do here is divide these

two fiscal years into one pre-9/11 period. The incident rate was 13.3 combined here. Down here the incidence rate was 12. These rates are per 10,000. Rate ratio slightly increased, not significant physically.

Over here in the post-9/11 period we see that the stress group, their incidence rate increased to 18.2. Over here we also saw an increase in the incidence rate among those who were not manpower stressed.

Looking at this the rate ratio here was 1.27 on the margins of statistical significance. So we see the cohort effect was mild and was mildly significant at best. We see the table of risk in the exposed group up here, the stress group. The part of the rate here in the pre period, pre-9/11 period was 1.3 injuries per 10,000. That was what was attributable to that exposure or these exposures.

What this represents really the latent exposures, latent risk factors. We don't know but we do know they were classified by manpower as manpower stressed. A lot of things come with that territory and we're not going to find those.

Over here in the post-9/11 period we see the risk attributable to or the portion of the rate

attributable to the exposure of being manpower stressed was 21 percent.

Let's look at the period effects. Moving from the pre-9/11 to the post-9/11, same rates as you saw in the other slide. Going from this period to this period in the stress group the rate increased marginally or moderately and it was significant. Down here the rate increased from period 1 to period 2 also. We see that this rate was slightly elevated between the periods and significant. These risks that you see are higher than they were in the previous slide.

This leads us to conclude that the period effects -- that was moving from pre-9/11 to post-9/11 were greater than the cohort effects of being either stressed officially or non-stressed. We saw that rates in the stress group were higher even before 9/11.

The period effect is moderate and it's significant stat wise in both periods. But the post-9/11 stress rate increased two time to that of the non-stressed rate. It tells us that we do have stresses that are incurred. All of these things that go on just don't affect the manpower stressed career fields.

They affect us all in the Air Force. Somewhat more so in the manpower stressed, but still the period effects are much stronger. Not much but significantly stronger than this cohort effect. Therefore, we can say with some validity that it's across the board.

We did the same thing for operational tempo, what frequency certain career fields deploy overseas. I didn't bother making slides but they show essentially the same thing. Very weak cohort effects, even stronger in this case period effects. Regardless of how you cut it, everybody in the Air Force is affected by this post-9/11 military upsurge.

At that point, there are more slides and I'll leave you to look at those hard copies and I will turn the floor over in a second to Ltc. Tom Luna who is our surgeon who will talk about the human factors efforts at the Safety Center. Any questions I can answer real quickly?

DR. LEMASTERS: I have one.

LTC. COPLEY: Yes.

DR. LEMASTERS: That's fascinating work and a wonderful surveillance system you have put together. You are to be commended for that. I just had one quick question. As you probably know, the Air Force

just completed a very large study of 10 bases on jet fuel exposures.

A lot of sampling was done at the end of the workday with fuel cell maintenance and tank maintenance for people and saw pretty high levels of fuels on the breath. I wondered if you had or could look at the data of those that occur after work like within an hour after the work hours. I'm talking about off duty.

But if there are any job categories where there might be some peaks because with some of these jobs like fuel cell maintenance, I mean, the solvent goes right to the brain and there is that intoxicating effect of those exposures. If they would also stop by and have a beer it's co-exposure.

Even with just the work place exposure, if you could look at those that occur right after work within an hour. Then are there any job classes where you see a high rate. I wonder if there is an intervention potential there.

LTC. COPLEY: Well, we do have the data. Exactly how we cut these things on and off duty, sometimes we don't know when a person is on or off duty simply by going by the time of day. In the military now we work pretty much around the clock.

There's a lot of people on shift work so it's something that happens at 6:30 in the evening or 7:00 in the evening.

No longer can we say like in the old days that's off duty or that was three hours after he got off from work. We do have a problem trying to determine exactly is this person working or are they off duty? We do have some data initiatives that will tell us more precisely their duty status at the time. We have on and off duty now but a lot of people confuse line of duty with on and off duty so that data is not really clean.

We are taking steps right now, as a matter of fact, to correct that to make it more precise and to clear up that confusion between duty status and line of duty. In other words, would your spouse get your benefits if you died. That's line of duty. Yes, we can --

DR. LEMASTERS: Even the time off duty might be --

LTC. COPLEY: Yes.

DR. LEMASTERS: If you could really capture that data.

LTC. COPLEY: Yes, we do have the capability to capture that and we do capture time. I have to say

on motorcycles because someone brought this up before about new motorcycles being bought. We have found a trend. It hasn't reach statistical significance yet but we are seeing that newly purchased motorcycles seem to be so prevalent in our population.

Someone threw that out a while ago and we are looking at that. We have thought about working with manufacturers and insurance policy people, insurance agencies to try to control this in some way. It's too easy to purchase a motorcycle. Too cheap. You don't have to pay for it for two years. That sort of thing.

Any other questions before I turn the floor over to Col. Luna? Thank you very much. Again, anymore questions, give me a yell.

DR. OSTROFF: Thank you. Col. Luna.

Can I just ask there may be somebody on the phone that's using a keyboard and if they could potentially put their phone on mute if it's possible.

COL. LUNA: Good morning. My name is Tom Luna and I'm the Air Force Safety Center surgeon. I was asked to come out here today and give you just a brief overview of who we are at the Safety Center.

You can't hear me? I'm Tom Luna with the Safety Center. I'm the Safety Center surgeon and I

was asked to come and tell you a little bit about what we do there on the life sciences side, how we look at data, give you a real brief example of how we've used our data, and what we're looking at for the future.

This is who we are. We have one physician there. That's myself. Normally board certified in both aerospace medicine and occupational medicine. That helps us to bridge the gap on the aviation side and the ground side. Also we are RAM so we have a masters of public health degree.

We have an aerospace physiologist and an aviation psychologist. We have a life support officer as well. We are located in the Aviation an Safety Division but we do consult throughout the Safety Center helping out on the ground side and weapons side as well.

These are things that we do. We spend a lot of time on the phone and via e-mail, as I guess a lot of you do as well, helping out the people in the field as they work through their safety programs, their prevention programs, as well as their investigations. We do a lot of consultation work for them.

We also do send people out on boards. We sent special consultants and subject matter experts out to the boards as well. We provide training to all

our investigators whether they be subject matter expert investigators or medical investigators looking at human factors. Or whether they are nonmedical people so that they can take part in the life sciences investigations and human factors investigations as well. We do that here at Kirtland Air Force Base, but also predominantly at Brooks Air Force Base in San Antonio.

We do something called an organizational safety assessment. I'm not going to talk about this to any great extent right now because we could talk about this for quite some time, but we find that a lot of our mishaps if you really trace them all the way back, there are some unit cultural issues at play.

What this helps us to do is go back and look at that for the commanders on a request only basis so that they know what their factors are and they can proactively take measures to address those factors.

Data isn't very good unless you share it. We put together newsletters for our life science personnel so that they can read in detail about what human factors were behind these mishaps so that they can be working on their local programs as well.

We also maintain a life science portion of our database. We will be looking at that in a moment.

That database includes predominately injuries, egress and life support information but, most importantly, human factors. That's where I'm going to spend most of the rest of this five or 10 minutes talking about our human factors to you.

Next slide. How to look at human factors. No. 1, let me back up and say we speak of human factors as the civilian community normally speaks of human error. Most of our mishaps, whether they be in aviation or ground or weapons, or human factors mishaps of some degree or another. They may have other important factors there but human factors are there in almost all of them.

We need to determine when we are investigating a mishap were human factors present and which ones were present. We define, okay, in this mishap they made a poor decision as far as risk. They took a risk that they shouldn't have taken. They should have used better judgment. That's one.

Then we'll say, okay, they have a problem with attention. They are channelizing their attention on one thing. That was a very important thing but they weren't scanning all their instruments. That's another human factor.

They were fatigued. They only got about

three hours sleep the night prior because their kids were up all night sick or something. Okay, we go through and we determine which human factors are present.

Well, human factors are very complicated and they interrelate. What human factor led to another one. What led up to the mishap. We put together this chain of events. The fatigue might not have directly caused the mishap but because of the fatigue, they probably made that wrong decision and took on too much risk. We start putting together and developing a matrix or a web of these human factors to try to determine how they influenced each other.

All human factors are not created equal in one mishap so we go ahead and we rate them on a scale of zero to four. The one to fours are pretty self-explanatory. Four is something that directly led to the mishap, one to three lesser importance and contributing factors.

We also rate some human factors as zero. What a zero means is, yes, it was present but, no, it did not play a role in this mishap. You may have a mishap where it was an engine problem that led to the crash of the aircraft. But in the course of the investigation we find out that the pilot was severely

fatigued. He still did everything that he was supposed to do. He recovered the aircraft or what have you.

But, you know, that fatigue may be important to when we're looking at fatigue issues in general throughout the Air Force, or for other mishaps. We still collect that information and we call it a zero. It was present. It was important but not relevant in this mishap sequence. That's how we rate them.

All of our human factors in the U.S. Air Force are defined. They have been defined for quite some time. They are all published in the Air Force Pamphlet 91-211. This way no matter which investigator is investigating we are still using the same language and we are still coding things the same way and that really helps us out as far as consistency is concerned.

Next slide. Just a few slides here to put some of these human factors in context. Once again, we work predominately on the aviation side in the Air Force Safety Center. For about the last 20 or 30 years, and as the slide shows the last 10 years in particular, about two-thirds of all of our mishaps have had causal human factors. Causal human factors.

Our data is not 100 percent complete yet but

it's looking as though over last year about three-quarters of all our mishaps were human factor mishaps. For those of us in the life science area, this is a big concern.

You know, you can engineer mechanical problems out of aircraft to a certain extent and a lot of that big decline you saw in the earlier slides that Tig Sullivan can be attributed to the fact that we can reengineer things. But, you know, we can't reengineer humans. We can train them better and we can give them systems to help them prioritize things and manage their tasks but, you know, we're still the model 1 human. That's going to be a continuing challenge for us.

Next slide. The previous slide was all Class A mishaps on the aviation side. We started looking at fatal mishaps and it's even more significant what our human factors cost is. In general over 90 percent of all our fatal aviation mishaps are due to human factors. Very rarely do we find a plane crash in the United States Air Force nowadays which is due to mechanical problems solely.

Next slide. Okay. Just an example on how we use some of this data at the safety center. Looking at one of our most important human factors,

spatial disorientation. Just real briefly what spatial disorientation is is you've got a crew or a pilot who loses track of the orientation of the aircraft.

Very often it's while they are in the weather. They can't see the horizon very well. They might not realize that they are flying at 90 degrees at bank or inverted. That's a bad thing, okay? Particularly if they don't know they are having a problem.

There's different types of spatial disorientation. In some cases you may know you are disoriented, in which case you could take action to at least get out of the aircraft. But in a lot of cases they don't know that and that is very dangerous obviously.

Our cost over this 10-year period, '91 to '00, 20 percent of all of our mishaps, 65 in total, were due to spatial disorientation. Almost $1.5 billion was due to spatial disorientation over that time period in the United States Air Force.

Almost 40 percent of all of our fatal mishaps over that period was due to spatial disorientation for 60 people in total. This is a big cost item for us and a lot of concern for us. What do

we learn when we start looking at this a little more deeply?

Next slide. Well, what we found is that over this 10-year period most of the contributing factors to spatial disorientation were cognitive factors. Disorders of attention or they made the wrong decision somewhere along the line. It may have been that they decided to take on too much risk or misprioritized things.

Then typically there was some weather problems there as well. The important thing here is that we found, and this is somewhat surprising, was that the most important contributing factor to spatial disorientation were cognitive factors.

Next slide. This is important because up to this point our training was predominately looking at sensory type of problems. Illusions, okay? Illusions are very common in aviation so we had good training programs for it. Well, you know, those training programs are probably doing the job.

People were not getting spatially disoriented to any great extent because they had been trained to expect those illusions and detect those illusions. So now what we're finding is that this is all cognitive.

What we need to start doing now is we need to start reorienting our spatial disorientation training programs to be looking at cognitive factors like making sure they do a good instrument scan to make sure they are not getting focused on one item in the cockpit. Potentially looking at our displays to help them to prioritize things and give them good warnings that they are in an improper orientation.

Next slide. Moving forward, where do we go to from here? Well, historically -- this is looking at data for fiscal year '00. You can take any year. That's when we started this big push. In fiscal year '00 add all this up there's about 4,000 mishaps or events in the United States Air Force tracked by the Air Force Safety Center.

If you look at all of those, this little wedge right here, these 22 were the only ones where we had full-scale in depth human factors data. Those are the only ones that we really investigated with people with a lot of training in human factors and were able to pull together a lot of detailed information that we can use for prevention programs.

Well, you know, what about the rest of these? We know that on the ground side we talked to our ground safety compatriots and they tell us that

almost all of those are human factors. One of the slides that Bruce presented looking at the off-duty mishaps, what I saw from that was only about two percent of them were due to some kind of mechanical problem.

All the others on that list whether it was fatigue, whether it driving left of center or what have you, those are all human factors. We know it's important there but we don't have detailed information from those mishaps looking at those human factors. And the same thing with weapons and all the way around.

So, you know, what we're thinking about is that we need to start moving towards collecting more information on these lesser grades of mishaps on human factors so that we can put together good programs to address these.

Next slide. And, once again, almost all mishaps have relevant human factors. When we look hard at it if we go back to five years ago, almost all of them have causal human factors. Obviously we want to do something about it. We want to develop good prevention programs. Programs need to be based on data and that data has to come from somewhere and it has to be investigated.

Next slide. So how do we get there? We're talking about going from collecting data on about 22 mishaps a year, or last year 35, up to close to 4,000. That gives a lot of people in the field a little bit of concern as you can expect.

How do we get there? Well, the big thing is AFSAS. AFSAS is going to make this possible because it's a nice web based data entry. It's real simple. In it we help to walk the investigator through. Whether they have a life science background or not help to walk them through the human factors investigation.

More importantly, to collect that data because we have been training them to do this investigation but we haven't been collecting it. Now this will give us a way to collect it easily from them so it's not real onerous for them and adding a large workload.

We are revising our safety courses, though, to bolster the human factors curriculum and make it simpler for them. Also make it easier for them to get a human factors expect to help them out when they need it. And we're going to do it step wise over a three-year period. We have already started on flight. We will be moving to the ground side and weapon side over

this three-year period so that we can learn as we go how well this is going, what kind of changes we need to make.

Next slide. We are not necessarily going to investigate any deeper. We are just going to collect the information so for our Class A mishaps where there is a fatality, a million dollars worth of damage, etc., we are still going to have a full-blown deep investigation. But for lesser grades of mishaps, Cs and Es, you've seen the definitions before, they won't need to investigate to the full depth and detail that we do for our Class As. But still we will be collecting that information.

Since this will be automated we'll also be able to use the previous five years of data once we have it to set automated levels, okay? The alert and detect levels so that we won't have to be saying, "Okay, is there a problem in fatigue?" If there's a problem in fatigue, it's going to jump up and we are going to have an alert telling us, "Hey, we're beginning to see an increase in our fatigue mishaps."

We don't necessarily have to ask the question. It should prompt us to let us know there's a problem in that area. And it will become a near real-time risk analysis tools as opposed to what we

have now where we are several months behind before we know what's going on.

Next slide. Obviously it's a huge undertaking but we think we're going to get a lot out of this. The Israelis in particular have gotten a lot of bang for their buck in looking at lesser grades of mishaps, looking at events to help prevent their mishaps. We are helping to be able to do the same thing.

Next slide. That's just real quick down and dirty what we do. A little example of how we use our data. Does anyone have any questions on any of this?

DR. OSTROFF: Thanks very much. I'll open it up to questions.

COL. LUNA: Yes, sir?

DR. PATRICK: What is the state of the art -- given this finding on the cognitive factors what is the state of the art of cognitive profiling of pilots, of actually determining who may be more at risk to make those errors in judgment and may not, and what factors might be intervenable upon?

COL. LUNA: I don't have the most recent data on that. I know that Brooks Air Force Base looks at the recruits. All the pilot trainees come through Brooks Air Force Base and they go through a very

extensive battery of tests to try to determine what their characteristics are.

Then they have also looked back over a number of years to see which personality profiles seem to be most at risk. Beyond that I really can't tell you details on it. I don't have that on the top of my head.

DR. PATRICK: It seemed like it would be interesting to sort of connect the dots between some of that because there may be a slight dose of ADHD disorder which is beneficial for pilots and a fitness factor that is just as important as whatever physical measures that we might assess.

COL. LUNA: That's right. I agree with you. Our aviation psychology cadre down near Brooks is running that program and I don't know the details of it at this point.

DR. OSTROFF: I have a question. It's probably a fairly sensitive issue, but you mentioned fairly consistently the issue of fatigue. I know that there's been a lot of attention paid recently to the issue of the use of stimulants to deal with fatigue factors.

I'm wondering whether you are collecting any data or information about that issue. If so, what

some of the things you're finding are. I guess the other question, I mean, it came as a bit of a surprise to me that some of the stimulants that were being used were actually allowed to be used and I'm wondering who sets that policy.

COL. LUNA: If I don't answer all parts of that, remind me and I'll readdress. As far as stimulants are concerned -- I will also look at the other side of that. 180 degrees off are our sedatives because we do have stimulants to help them to make it on long-distance missions, particularly when they are flying alone. We also use no-go pills such as Restoril and Ambien to help them to cope with jet lag and to be able to get sleep in their new locations so they are better rested.

For some period of time we've had a code specifically for medications prescribed by a physician. Both of those fall into that -- would be coded under that. We went back and periodically over a time we've done this because this issue continually comes back up. We have looked at that and we have no events or mishaps attributed to either go pills such as Dexatrin or no-go pills, Restoril or Ambien over time. That's No. 1.

Fatigue we've been looking at very closely

as well. Fatigue is very important. However, when we look at our data we have some mishaps that are directly attributed to fatigue where fatigue was causal to the mishap. But much more commonly -- let me say that is actually fairly rare that was the factor that the mishap investigators found caused the mishap.

What we have found, though, is that fatigue sets up mishaps. It's one of those contributing factors. It helps to set up problems of judgment, problems of attention, and things like that. In that way we find that fatigue is very important.

That's where our data has taken us in that regard. Going back over close to 30 years we found that a little over 7 percent of our mishaps fatigue was found to be a contributing factor. Class A mishaps.

I think there was another part to your question, though.

DR. PATRICK: The policy.

COL. LUNA: Policy. Policy comes from AFMOA. They generate it with research from the Air Force Research Lab. That is also staffed through the line side, the actual aviators themselves. Everybody has say into it.

I know there was a period during the '90s where the medic said, "Hey, we've got this tool. We think it's safe." The line side wasn't so sure about it. There are checks and balances in that whole program. There may be other people here that might know that process a little better from AFMOA. Col. Cropper or some of the others may be familiar with everyone else that gets to weigh in on those decisions. In general it comes from AFMOA.

Yes, ma'am.

DR. FORSTER: How much do you think you can actually improve the cognitive deficits or factors that seem to be contributing to these incidents?

COL. LUNA: Boy, that's tough. That is difficult. One of the things that -- the way I look at this is that our modern aircraft, particularly our modern fighter aircraft, are asking just a tremendous amount from our pilots, from our crews. There are many things that they are asked to attend to. There's two ways of helping them through that.

One is through training. Better training, what to look for, when to recognize problems, etc. But I think that's going to be limited. That's going to be limited. The other part of that is working on the systems themselves and the displays and the

computer displays. You know, I don't know how far we can go in that realm either.

We also are trying to go through not just displays but oral warnings and visual types of displays. Particularly the Navy has come a long way in developing some tactile types of things. They have a tactile vest. So we're talking about spatial disorientation where the pilot loses a sense of their orientation in flight.

Well, historically the way a pilot has gotten that information is by looking at displays, looking outside the cockpit and seeing the horizon. But also looking at their displays to see the instruments there.

What the tactile vest does is it actually gives them the sensation on their torso of where the horizon is. We are finding that is also -- we haven't fielded that in the Air Force. However, that is another way for us to try to address those types of problems.

We have really been surprised with the ability just using tactile cues alone for a pilot to be able to fly the aircraft. Even a helicopter. I've heard about helicopter pilots being able to hover an aircraft blindfolded and not being able to see their

instrument just because the tactile cues are on their torso.

Bottom line, it's going to be difficult and we have to be creative in looking at things such as tactile things. Training as well as improving our displays and trying to prioritize things for the pilot and crew.

DR. FORSTER: I'm glad to hear that. You are focusing on things other than trying to improve people's judgment, risk perception, and that sort of thing. I think that is probably limited.

COL. LUNA: I think so.

DR. OSTROFF: Thanks very much. We're running a little bit behind so I think what we'll do now is go to our break. It's just before 10:00. It's 5 of 10:00 so why don't we plan to come back at, say, let's take a 10-minute break and then we'll come back and we'll enter the phase where we have several questions to the Board.

Thank you. Excellent presentations.

(Whereupon, at 9:55 a.m. off the record until 10:15 a.m.)

DR. OSTROFF: Our next series of presentations have to do with questions that have been put before the Board by Dr. Winkenwerder asking the

AFEB to perform as an advisory body to several different DOD centers. We have presentations on those centers and it's nice to have presentations by folks that we're so familiar with. The first one will be by Cdr. Ryan. It's good to see you again. We look forward to your presentation.

COL. RIDDLE: Her slides and the questions are in front of you on the table. They are available over here for other folks in the audience that might want them on the table.

CDR. RYAN: Thank you, Dr. Ostroff. Again, it's an honor to present to the Board. The Board, we were very privileged to have them come out to San Diego just about a year ago. Many of you are familiar with some of this. I'm going to skip through rather quickly what I think we've been through before. Also for the sake of time. Again, all of the information is on the slides that you have as handouts.

This is sort of special for me because this is the first time to present to the AFEB as now our advisory body to the DOD Center for Deployment Health Research. Just as a review, the DOD Center, our group in San Diego, performs epi studies that relate to the health of military members and their families.

We also have a focus on emerging infectious

disease issues. I am going to hand the mike over to my colleague, Dr. Russell, for the mid-section here where we talk about particularly the infectious disease issues because he heads our laboratory there.

We have 75 professionals on our team and 30 active protocols right now. We are the largest group at the Naval Health Research Center and possibly the largest single epi group in the Department of Defense.

A lot of our origin is based on the legacy of the first Gulf War in 1991. Of course, after that war there were multiple expert review panels an DOD registries and VA work and extensive management into the questions about health problems in that post-deployment era. Those post-deployment health problems cost the military and the Department of Veterans Affairs and the country quite a bit in terms of intensive looks at what was potentially hurting our veterans who had deployed.

At the Naval Health Research Center under the direction of Cap. Gray -- Dr. Gray, quite a few studies, large epidemiologic studies were performed, studies related to hospitalizations, symptomatology, review of the major publications, and reproductive health effects.

Because of that body of work, when the DOD

Centers for Deployment Health were stood up in 1999, the Research Center was designed to be at the Naval Health Research Center to be that group at Naval Health Research Center.

The Clinical Center at Walter Reed, and Dr. Engel is going to speak after we are this morning, and then the Surveillance Center at the Army site in Aberdeen, Maryland. So we were quite honored to be sort of labeled the DOD Center for Deployment Health Research formally in 1999.

We certainly don't act alone. We work with quite a number of collaborators and I've listed them here for you. Many within the Department of Defense and many academic collaborators, of course, outside of the Department of Defense. We very much value both collaboration and consultation of our academic peers, especially the Armed Forces Epidemiological Board.

These are the projects. Again, I said there are 30 active protocols but these are the major projects that we have on the table right now at the center. There are still a number of Gulf War kinds of looks because we probably will never finish completely talking about the first Persian Gulf War.

We are going to spend a little time talking about the major foci here, the emerging infectious

disease studies of which there are many. We won't be able to do justice to them all but to give you a flavor for the major efforts there. The Birth and Infant Health Registry, which we've talked about before, the Recruit Assessment Program, and then the largest study within our team, the Millennium Cohort Study.

I'm going to turn the mike over to Dr. Russell for this mid-section on infectious disease.

CDR. RUSSELL: Good morning. Is my mike on? Can you hear me okay? Good morning. It is a pleasure to have the opportunity to talk to the Board once again. I'm just going to cover a few slides on out infectious disease study as Dr. Ryan mentioned.

We have a very unique facility here which Dr. Gray built in the middle 1990s. As many of you are aware, it has some very unique capabilities in diagnosis of respiratory pathogens. Most notably, adenovirus.

The lab was first built because of the need to follow what happened after the adenovirus vaccine was no longer available in recruit camps. That has been enormously successful and this Board is very familiar with some of that data. I'll show you a little bit of that.

A variety of other respiratory pathogens including Group A streptococcus. Our lab has been very involved in the outbreak of Group A streptococcus in the Marine recruits in San Diego which got quite a lot of national media attention.

Our surveillance for viral pathogens, our febrile respiratory infection surveillance projects are at nine different group training centers throughout the United States. Those are the blue stars. The strength of this surveillance is the fact that we have staff at each of these sites that do this surveillance for us.

The streptococcus pyogenes, the streptococcus pneumoniae surveillance efforts, our military treatment facilities. They send us islets that they get at various places throughout the United States and we characterize that from antibiotic susceptibility to molecular work on those. The pneumococcal vaccine trial, I briefed this committee on about a year ago and that is still ongoing. I'll talk about that briefly. And Pertussis.

This is some of the data that we do put forth on the Internet site. This is the results of some of our surveillance efforts at the recruit training sites. You can see the running rate of

respiratory illnesses at different sites. 1.5 cases per 100 trainees per week is the static threshold for an epidemic that's been used historically. That was very notably exceeded frequently after the adenovirus vaccine disappeared, which you all are familiar with.

Also available there is the actual results of our testing at each of the different sites. You see here MCRD San Diego, Great Lakes, Ft. Jackson. The adenovirus is the red portion here at the bottom of each of the columns. Some influenza. A very highly vaccinated population here in the recruit centers but still some influenza. Others such as respiratory sufficial virus are also identified. The green here at the top are unidentified febrile respiratory illnesses.

One of the exciting things that we've been expanding in in the last year is expanding this FRI surveillance from the recruit camps to floating platforms. We are currently on board five ships. All of these ships are now involved in deployment to Southwest Asia.

USS Nimitz, a large aircraft carrier, will have on board when the full flight compliment is there 4,500. A couple of these others are amphibious ships that have large Marine attachments to them. Have

different exposures. Very interesting important surveillance we feel.

The other strength of doing some of this surveillance is the amphibious ships have -70 capability so collection of samples that can be stored appropriate for further classic culture is possible. The ships that do not have -70 capability we have liquid nitrogen tanks on board to collect samples appropriately.

We have also supported the Forward Preventive Medicine Unit that is actually in the process of leaving right now in support of Southwest Asia deployments. We have provided the Nimitz as well as the Forward Deployable Preventive Medicine Unit with some diagnostic capability for both adenovirus, influenza A, and influenza B.

This has been a pretty large effort on our part over the last several months in order to get this to a point that it was usable by these organizations, that it was simply used and reliable. AFIERA has provided a lot of collaboration and expertise to the design of the primers. Just wonderful collaboration with them. They have designed a lot of this but hadn't had the opportunity to really test it yet. We have done that over the last several months.

What was developed was a life cycle of capability because the aircraft carriers on the west coast have life cyclers on board. Forward Deployable Preventive Medicine Unit has a life cycler they are taking with them.

What we have developed is a cyber green realtime PCR method of identifying adenovirus and influenza A an B. It's a pretty strong capability because not only do you have the real time PCR of identifying whether or not your pathogen is there, you can then go back with the product, do a melting curve, and for the one PCR, for example, for the adenovirus the melting curve will give some pretty good and strong information about the serotype of adenovirus depending on where that DNA melts and the fluorescence is lost. This is a life cycler.

The influenza we successfully multiplexed from original patient specimens so you do both A and B in the same tube and the melting curve tells you whether it's A or B.

Some other emerging infectious disease projects that we're embarking on right now is a lot of expansion of our molecular projects. Break-through adenovirus infections from the archive of samples that were collected in the early adenovirus surveillance at

our recruit training centers. There are quite a few individuals that came down with adenovirus infection after they received the oral vaccine.

We pulled these aside and we're looking at them actually in our final stages of doing phylogeny analysis of these islets as compared to individuals that did not have the vaccine and had an adenovirus infection both 4 and 7.

The development of multi-locus sequence typing is something else we've spent a lot of time on. It's now developed for streptococcus pneumoniae, Group A streptococcus, as well as methocylin resistant staphylococcus arias.

A year ago I reported to the Board that we had an unfortunate but interesting case where an individual did succumb from a meningitis that appeared to be caused by streptococcus pneumoniae and it appeared to be unencapsulated which was pointed out and is well known to be very unusual for an unencapsulated organism to be so virulent.

Dr. Muster confirmed that it appeared to be an unencapsulated pathogen. As I was talking to him about further analysis of this islet he said we really need to do multi-level sequence typing on it. We developed that over the ensuing months and that multi-

locus sequence typing analysis showed it to be serotype 38. It was simply an emerging serotype that wasn't generally included in his or our serotype being processed.

So it was not unencapsulated but it was an emerging serotype. It's a strong capability. We've been using this for the group base streptococcus outbreak in San Diego, as well as for the methocylin resistant staph. arias outbreak that has been affecting many populations in the military.

Lastly, I just want to talk briefly about some partnering with various organizations that are developing some very novel diagnostic techniques. Clearly PCR has been absolutely groundbreaking in diagnostics over the past decade.

However, to do PCR you have to, one, have knowledge of the organism you're looking for, the sequence of that to design primers that will target it, as well as the fact that it's largely a one pathogen, one run look. One sample, one pathogen, one run. There's some multiplex but it's not particularly strong.

Some of these newer diagnostic techniques are trying to look at high through-put for multiple organisms simultaneously. One of them does a PCR

front-in but it's using primers that are directed toward highly conserved regions of bacteria, for example, or u-carryouts so that the amplicon that's created might differ depending, or would differ depending on the pathogen and the pathogen that is actually there.

Amplicon is sprayed into a mass spectrometer that is sensitive to molecular weight up to 3 electrons so it can tell you the composition of base pairs in that amplicon usually with no -- usually there is only one combination of base pairs that would result in that molecular weight. Then often that has been specific for a particular pathogen.

We have been using this in collaboration with the civilian organizations that are developing this to look at some of our adenoviruses for serotyping our adenovirus. They were also very involved in our group base streptococcus outbreak investigation because they had the capability of within 12 hours looking at hundreds of samples for hundreds of organisms.

We developed this to show some very strong association with different clones of Group A streptococcus which we thought we might need if this outbreak spread anymore than it had at the particular

time.

This is a four-dimensional chart that results from this mass spectrometry analysis. Here are three dimensions, the fourth one being the size of the molecule. Again, showing a lot of promise. The other technique is microarrays and we are involved in the EOS calibrated surveillance program and looking at that.

Next. The pneumococcal vaccine trial. Again, I briefed this committee on it a year ago. It is still ongoing. We've had challenges over the last year. We look in the next month to finishing up this trial. Over 140,000 people enrolled in this.

This Armed Forces Epidemiology Board -- the endorsement of the Armed Forces Epidemiology Board really was critical in development, implementing this trial. We are thankful to you for that. Hopefully some good information is going to come from that.

Next. Again, there are quite a few peer-reviewed publications that have come from the respiratory disease work. We hope to continue in this tradition.

Dr. Ryan.

DR. OSTROFF: Thanks.

CDR. RYAN: Again, we are conscious of the

time and I wanted to make sure that hopefully we have enough time to talk about the infectious disease work which is so exciting and really is the legacy of Dr. Gray.

We've talked about the Birth and Infant Health Registry before but I know there continues to be interest here. This slide shows there is strong background when you get into the post-Gulf War era to develop this birth defect surveillance system.

Why do we want to watch birth defects? Because they are common, they are costly, and they are extraordinarily concerning. The CDC and the states do birth defect surveillance at least in 35 states. But for many reasons the Department of Defense can do this extremely well. In many cases better than other systems.

The reason we can do that is because we have so many data sources that are standardized and that are accessible to us. We have visibility on all of the births of all of the babies to military families. We have visibility on both their birth to demographic factors and then their diagnoses in the first year of life.

What do we find when we look at all those data? 90,000 to 95,000 births per year, which makes

it a very large system and it's very complete capture of those data. 19 percent of those babies are born to active duty women. The majority are born, of course, to wives of active duty people.

The military births take place all over the country and, to some extent, all over the world. There's more than 20 foreign countries where military births take place. Really in terms of a surveillance system has some interesting visibility there. We can link again to demographic, occupational, and military exposure data. At least some of those data that are concerned when we talk about potentially things that are associated with adverse reproductive outcomes.

What do we find? Overall there's 3.2 percent of military births are affected by major congenital abnomally. That's very consistent with civilian data and factors associated with those adverse outcomes. Including advanced maternal age and so on are also very consistent with what is seen in the civilian world.

Limitations, of course, is that this is surveillance of live births. We can't capture defects in miscarriages or still births, and we can't and don't capture diagnoses after the first year of life. That makes us consistent with other surveillance

systems. Even though that is a limitation, it's important that we remain consistent. It is the way that we can best define these data both in terms of the enumerators and denominators, if you will.

The strengths again is that we have complete capture. We have quite a bit of records that we can review. We have some validation of the electronic records done by hand that show us that the data are extremely valid. We have the ability to link to these other systems that make this a valuable resource.

We do annual reports. We contribute to the National Birth Defect Prevention Network. That's the U.S. state surveillance, CDC surveillance. Then, finally, I want to mention again another place where the Armed Force Epi. Board has really been a great asset to us and has really helped us, one of the first linkages of the birth surveillance system to an exposure of interest was to anthrax vaccination, so maternal anthrax vaccination.

Many of you on the Board I am extremely grateful to for continuing to help us in sorting this out because our original evaluation was quite provocative, contributed to some reports on anthrax vaccine and reproductive outcomes that are of concern to military members.

It prompted a large validation effort, validation of both anthrax vaccine data and of the birth defect surveillance data. The anthrax vaccine validation, which has been quite a rigorous effort that we have pursued in the last 12 months, has progressed.

At another point I know the Board is planning to hear about that. That's important to the military, especially as we move into future deployments and we rely on these vaccine data for smallpox vaccine and other exposures.

Just a few words on the Recruit Assessment Program. Col. Gibson tomorrow is going to present on this so I'm really not going to spend time here, but just to say that we are continuing to be involved in the Recruit Assessment Program. This is all about collecting baseline data on recruits. Everybody appreciates how important those baseline data are. They are not available until the Recruit Assessment program was stood up.

Collects demographic data and all of the sort of pre-exposure data of interest, if you will, or baseline data of interest. We've done a lot of work at the Marine Corps Recruit Depo honing this instrument to collect these data.

Right now we are currently about 18 months after being fully implemented at the Marine Corps Recruit Depo which has resulted in a large amount of data for us to analyze and help hone the instruments as well as to comment on what those data show.

There are some examples again that are in your handout. These are sort of interesting things about what these young adults joining the Marine Corps tell us when they come in in terms of their environments that they've come from and their potential health risk factors before coming in.

We spend a lot of time -- Col. Riddle will be pleased to know I'm not going to spend time on this slide, but to tell you we spend a lot of time looking closely at these data -- again, this is still a pilot program because this is not DOD wide -- looking at re-test specifics and specific questions of interest so that we really hone the survey the best we can since the goal is for this to be implemented DOD wide. Again, Col. Gibson is going to spend time tomorrow talking about that progress.

To wrap up our contributions to the Recruit Assessment Program, well underway in San Diego, sharing what we're doing with Ft. Jackson and the other recruit camps, and really get quite a bit of

interest from our colleagues in Canada and Australia on this program.

Finally, a few slides on the Millennium Cohort Study. Our largest effort in the DOD Center for Deployment Health Research. Again, a study that the Armed Forces Epidemiological Board both as a group and individual members have contributed to tremendously.

Millennium Cohort has a background that also related to the post-Gulf War era. There is a recognized need to do longitudinal prospective study of the military so we can better assess deployment effects on how and, again, sort of a Framingham model, if you will, of looking at military health.

Primary objective is to look at chronic disease outcomes or long-term outcomes. This is a long-term effort. Even the multi-symptom illnesses within a cohort over 20 years. Again, a secondary objective is looking at the things that were hard to define in the Gulf War era, functional health status symptoms over time.

What we're doing is enrolling a large cohort. It was a stratified random sample among all of the people in the U.S. military who were on board in October of 2000. The plan is to resurvey them to

get subjective data every three years for up to 20 years.

New accessions will be added to the cohort in 2004/2007 and will link to objective data on exposures and health outcomes throughout those 20 years at the scheme of how people are enrolled. We are just completing initial enrollment of the initial cohort and then we're adding new accession cohorts at two other points in time, 2004 and 2007, and we'll follow all the way out to 2022. Very large effort which at this point we spent most of our time setting up because it's extremely important that we set this up as well as we can because it's such a long-term effort.

The data that will be linked to the cohort who has consented to enroll and include all of these objective data, deployment issues and demographics, exposures like immunizations, outcomes like hospitalizations, birth defects, morbidity, and mortality.

Again, we sent a lot of time enrolling so far. We have sent out our invitations and we have spent a lot of time talking about getting our enrollment rate as high as we can so that it's as representative a sample as it can possibly be. But

thinking about retention because we need to retain these folks, this large number of people in our cohort to work with us, so to speak, for the next 20 years.

Again, that's our Veteran's Day card which is a retention effort. It says, "Happy Veteran's Day. Thanks for contributing to the Millennium Cohort." They will get another card on Memorial Day and they will keep hearing from us to have that identity of being part of the Millennium Cohort.

This is our website. We really just enjoyed working with the website because the website not only has great information and so on and tells people what's going on but gives them the opportunity to get information, general information on line about enrollment, but also to enroll and contribute their data in a secure fashion on line which has been a tremendous asset to making this work on such a large scale.

We've really benefitted from some marketing consultation which is new for us. That has really contributed to us having a well-received website. This is an incentive to use the website, a phone card. That's worked very well.

Currently we are completing the initial enrollment. We were challenged in the very first

months of enrollment by the terrorists attacks of September 11th. That did kind of impede our plan for enrollment a little bit. We also had anthrax in the U.S. mail system which really put a crimp in trying to do mail surveyed enrollment.

That's another reason the website was so valuable. We have actually now 78,000 members enrolled in the cohort and we expect the complement to 140,000 by 2007. Our Internet enrollment, enrollment over the website, is more than 50 percent.

A little bit of look at data. One of the reasons why I say that completing the survey on the Internet, or enrollment on the Internet is a wonderful thing, not only are the data clean and complete. This shows completion rate by questions. They are very easy for us to analyze. Just a myriad of things that are superior about enrolling over the Internet, the secure website.

In the paper survey, although we use an advanced software capability called Teleform to get these surveys done and scanned in accurately and cleanly, it's still much, much more efficient to do it over the Internet.

This is 90 percent here so you can see completion rates are actually quite strong in both the

paper survey and the Internet survey. They are superior over the website.

An awful lot of people help us with the Millennium Cohort, as it should be. Again, it's a 20-year effort. Co-investors from all the services and the Department of Veterans Affairs. We've got a lot of external consultation into the protocols. Multiple IRB reviews with all of our organizations. We have an external review by the American Institute of Biological Sciences about every 18 months.

We are now privileged to have AFEB review that I have indicated as annually by Col. Riddle's indication of reviewing the DOD center in general. Then we have a specific scientific steering and advisory committee that many of you are already familiar with who at least annually, and generally more often, spends quite a bit of time helping us to make sure that the science is strong.

A little bit of press on the Millennium Cohort that we hope is recognized as important to the Department of Defense.

Then finally just a few wrap-up slides here. The time is gone. On our question to the Board, to the AFEB, as an advisory body to the DOD Center for Deployment Health Research, we really didn't come with

a question to the Board, specific question to be answered.

I want to again say how much we valued the Armed Forces Epi. Board being a proponent of various projects over time; the Recruit Assessment Program, the Millennium Cohort, the Birth Registry work, the pneumococcal vaccine trial, other infectious disease studies in our center. It really has been quite powerful and important to us.

Looking at the direction of our research in general is valuable to us to have the Armed Forces Epi. Board give any thoughts or opinions or comments that they have on the overall scheme of our research and direction we're taking.

In the future we've been asked to look at smallpox vaccine because certainly already recognized to be an issue of concern to the military. We have experience looking at anthrax vaccine and health effects, both long-term health effects and reproductive health effects.

We expect to be looking at if another Southwest Asia deployment, large-scale deployment and engagement happens -- forgive me for putting in a Gulf War II there -- if some engagement happens in Southwest Asia, there will likely be post-deployment

concerns.

Our Recruit Assessment Program will allow us to have some baseline data on a large number of Marines who have deployed to that area. We have considered looking at that longitudinally after such a deployment.

Certainly we continue to talk about collaborative work on the Millennium Cohort with a number of other groups, folks who are concerned about bromide exposures, other vaccine exposures, the other environmental exposures in that region, or general deployment health issues.

Again, we value your thoughts tremendously. The recommendations of the AFEB often drive research and resources. Your comments on both that and collaborations are of tremendous value to us.

I always have the picture slide of the team that I'm privileged to work with. This is about 45 of the 75 folks who are on our team. We are lucky to live in sunny San Diego.

DR. OSTROFF: Thanks very much. Let's open it to questions from the group.

Dr. Berg.

DR. BERG: Megan, in about a month HIPA goes into effect which has tremendous implications for

medical databases. How is that going to affect the center?

CDR. RYAN: So far so good in terms of HIPA issues. Our institutional review boards and the other institutional review boards are struggling with how HIPA will affect all research. We expect that we'll be able to meet requirements that the IRBs may impose on us in relation to HIPA as they come up.

It is a concern but it's a target which is not well defined for us at this point in terms of what impact it will have. There has been certainly some consideration that the impact may not be so great upon the Department of Defense or the Department of Veterans Affairs as it will on the Department of Health and Human Services, for example. We are quite cognitive of it being a potential impact to us in terms of collecting these data.

DR. BERG: Thank you.

DR. PATRICK: Megan, a very impressive presentation. What I'm wondering, I want to kind of connect what you have described here with an observation that came in the earlier presentation on the incomplete public health model in DOD related to we can identify issues and we can monitor the results of intervention affects. It seems like essentially

interventional research might be less emphasized than more of the surveillance and epidemiological descriptive kinds of things. Is it the role of your group or the clinical group or the surveillance group to fill in some of that and/or what plans might be underway to essentially do more of that kind of stuff and factor it into the ongoing processes that are involved here?

CDR. RYAN: That's an interesting question. When we think about clinical -- for example, clinical interventions for deployment health concerns, there actually was some vision in the planning of the Deployment Health Centers that clinical research would be with Col. Engel's group at Walter Reed and the long-term epidemiologic studies with our group, although we have worked together clearly on several studies.

In terms of other interventional work we've certainly done some of that as in the pneumococcal vaccine trial. You are right that the vast majority of our portfolio is on observational epi. studies and not interventional studies.

We do have a little clinical trial center -- I shouldn't call it little because it's quite a bit of work -- where we collaborated on clinical trials with

the Department of Veteran's Affairs. There is some look there but in terms of who decides where the resources should go, much of that is driven by the stakeholders and the people who fund the studies.

At the highest levels of the Department of Defense and the Department of Veteran's Affairs we'll see whether there's drive for some specific intervention or whether a large epi. study is more important.

DR. PATRICK: When I see this division between the clinical and research and medical surveillance, when I think clinical I typically think numerator rather than denominator, rather than sort of general overall public health types of interventions. I think it's a real policy issue. Care should be taken to not lose the concept that some of perhaps the most productive clinical/public health research and intervention research may well really bridge your unit and their unit.

Again, you've asked for our advice and I think this is an important area that might take great care to assure that it happens. We have heard this morning there are problems that probably are going to take very much a denominator approach to addressing rather than just clinical environments.

DR. OSTROFF: Let me ask the $64,000. Since the genesis of your center arose from problems that occurred with Gulf War I, now that we're approaching Gulf War II, that's the way that I'll look at it, are you comfortable that we have the data systems in place to make sure that we don't have some of the interpretive problems that we saw after Gulf War I?

CDR. RYAN: I don't think that any single study is going to be the answer to all of the questions that might come up in the next deployment. I think the Millennium Cohort goes a long way to help it.

The Recruit Assessment Program -- candidly, I wish the Recruit Assessment Program was in place at every boot camp and had been in place for the last five years so that all the deployers right now would have the same baseline data. No, not completely do we have everything that everybody would like but it's much, much better than it was in 1989/90 before the last major deployment to Southwest Asia.

Are we ready for all issues? I don't think any of us will ever feel that confident to say we are ready for all issues but we are much better prepared, I think, than we were 12 years ago.

DR. HERBOLD: One observation. When Col.

Copley was briefing on the Air Force Safety Center and talking about one of the missing links it was a lack of having the authority to implement intervention plans or programs which involves the line of the Air Force and of the safety community.

I note on the list of research collaborators that they are predominately, if not all, medical units. Has there been some thought to having an advisory board of line and potentially a congressional involvement to assist in the long-term survival of these programs?

CDR. RYAN: That's an excellent question. Perhaps they do it justice on the collaborator's slide. We actually get reviewed as a defense technical objective, it's called MD-25, annually through something called the TARA, Technical Area Review and Assessment Program. The acronym may sound meaningless but it's a large Department of Defense review on all military research investments, if you will.

And it's not just medical. The folks who are reviewing us, the professionals reviewing us, are congressional and lineside leaders who are making decisions in terms of resources about whether or not this is what we want to do and who should be talking

to whom for this kind of work. There really is lineside or operational side input into sort of the foundation of what ends of being our resources. And on a more local level, we work closely with lineside communities on some of our work.

I know Dr. Russell couldn't even begin to put that slide up of an aircraft carrier if he wasn't talking to the commanding officer of that carrier. There's a lot of line community. Easier for us within the Navy locally but we're certainly sensitive to the fact that we have to be responsive to the operational community lineside.

DR. OSTROFF: Let me just ask one more quick question and then we'll move on to the next presentation.

Commander Russell, you said there were some difficulties with the pneumococcal vaccine trial.

CDR. RUSSELL: Yes, sir. Over the last year Wyeth has stopped production of their product, which you probably are aware of. The product for our study was no exception. They have apparently produced more vaccine for us but it is going through multiple quality control hurdles and we continue to be put off on when the Wyeth product will be available again.

We have successfully implemented purchasing

the Merck vaccine which is generally felt to be a comparable product and are using that currently in our study. That is probably the biggest hurdle we've gotten through over the last year.

Naturally there were all sorts of IRB issues. We had a lot of challenges at Great Lakes. Not particularly because of our study but because of their IRB approval process there which gave a lot of delays to our study.

And we have ongoing challenges of how much pneumococcal illness there actually is in the population. Currently in our unblindings we are seeing very little effect of the vaccine for all cause of pneumonias. We are getting a lot of permatory, laboratory health from the CDC on exactly what out burden is.

DR. OSTROFF: Thanks. Why don't we move on to Col. Engel.

COL. ENGEL: How well can you hear me?

DR. OSTROFF: We can hear you just fine.

COL. ENGEL: Okay. Great.

COL. RIDDLE: Megan made it in 25 minutes, Chuck, so I'm going to set the clock here.

COL. ENGEL: Pardon me?

COL. RIDDLE: Megan made it in 25 minutes so

you've got a tough standard here.

COL. ENGEL: That's bologna because I've been on here.

Okay. I'm just hoping that my kids won't burst into the room in the middle of this. I couldn't get to the office. In fact, my next door neighbor managed to get his Toyota Landcruiser stuck out in front of our house so that kind of gives you an idea of what it's like here.

In any case, I'll go ahead and start. Are the slides up?

DR. OSTROFF: Yes.

COL. ENGEL: Go to the second slide entitled "Request for AFEB Advice." I would like to sort of start out with what it is that we are interested in knowing. Certainly your advice can extend beyond these questions. We would love to hear the ideas that you might have, but these are some specifics that we thought would be important for us to hear.

One is advice on population health care models and clinical epi. methods for improving deployment related health care. All of this will be obviously in the context of what I'm going to present to you after this slide.

Also, we have a need as I would describe as

an ongoing need for review of our various mission elements and to what degree we emphasize each. Naturally there's external pressures that we feel in various aspects of our mission which in the long run may not be necessarily the best thing for us to be doing. It helps for us to have external advice that keeps us sort of on track in a long-term way.

We are also interested in analogous activities on which we can model our activity. Are there other activities in the civilian sector such as -- I'm aware of the evidence-based practice centers that arc funds. To some degree what we're doing is similar to that, although not the same.

Then also we're interested in ways that AFEB might recommend or facilitate collaborations with other federal departments. I say specifically the VA we're interested in and the Centers of Excellence that they have in related areas.

If you go to the next slide, it just offers a quick overview. Given the time I'm just going to skip over it. I know that pretty much the folks that are listening have heard me present on this before. I won't belabor some of the historical aspects of things that you've heard before but I do want to cover them.

We started out as the Gulf War Health Center

in 1994 when the Department of Defense started what was called the Comprehensive Clinical Evaluation Program for Gulf War veterans' health concerns. That was modeled after the VA's Persian Gulf veterans' registry.

The next slide shows what became some positive publicity around a unique element that we ran at our center which was essentially a tertiary care referral intervention for people with serious but medically unexplained physical symptoms, serious in that they often drove disability.

Quite honestly serious in some cases because they complained to people in high places that they weren't getting their needs met through the existing health care system. We went to great lengths to assist them and got some positive publicity and some positive results in assisting them.

While all this was going on, the next slide shows that we were gaining a sort of new understanding. We were re-remembering the fact that thee sorts of symptom syndromes after war were common.

You go to the next slide you'll see recent symptom syndromes that involve military disaster or terrorism. In the second column, lower right-hand corner you'll notice -- in fact, when I spoke to the

AFEB before I had a slide that showed that there were people within days already raising concerns about exposures and their impact on health and how this could manifest as medically unexplained symptoms.

November Newsweek had an article on something that it called World Trade Center Syndrome. We have seen an escalation of those concerns. There have been symptoms in people who are concerned about anthrax exposures. We've also seen health concerns related to irradiated mail that was intended to protect people anthrax.

The next slide shows a more recent development that's not widely known but there was concern at one point about environmental exposure at an Uzbek base. There were some troops, largely Air Force, that returned and had symptoms that they related to exposures that careful testing was not able to replicate. We were left in the situation of not really having any clear exposure that we were aware of. Nevertheless, news had gone out. People were developing symptoms and concerns related to that.

The next slide really shows what anyone who has practiced clinical medicine already knows. Probably a lot of people who have just seen a doctor already know and that is that there are many things

that doctors can't explain. Doctors don't necessarily like to advertise that back. It's probably not a good business principle. They apply fancy names to a lot of these things which implies that they know more about them than they necessarily to.

The next slide really just gets at this issue that we've been talking about, which is if these sorts of symptoms are common and these concerns are common, what's the big deal? Why should we think about post-deployment care as any different from other "routine primary" care that's delivered.

The next slide really is obviously rhetorical. It is attempting to show that certainly in the general public's eye any attempt to minimize the hazards of our work place just doesn't pass the common sense test. Certainly over time we've done some things to shoot ourselves in the foot which arguably may have been acceptable at the time, but certainly now they offend our sensibility such as nuclear testing and testing with chemical agents as late as the '70s in Hawaii. These have only exacerbated health concerns related to more recent things like Gulf War and the anthrax vaccination.

The next slide emphasizes that in clinical medicine there is this large interpretive space or

interpretive gap which is between what is a plausible cause of any patient's symptom and a proven cause of any patient's symptom. Often in clinical medicine studies show that about a third of patients present with medically unexplained symptoms.

They are in that middle area. The clinicians tend to ascribe these sorts of symptoms to stress. If there is any mistrust or misgivings about the honesty of the provider, and sometimes even if there is trust, the sense on the part of the patient is that their problems are being diminished which can yield a bad outcome, even if it's true.

That's not to say it's always true but the point is if you can't make the intervention acceptable to the patient or the explanation acceptable to the patient, it disrupts care. It doesn't enhance it.

The next slide shows a study that we did in VA providers in thinking about Gulf War illness which only highlights what I'm saying. We compared internists to mental health professionals in their model of cause and treatment for Gulf War illness.

While there was substantial agreement, there was definitely disagreement in the direction across the two specialties in the direction of internists seeing these sorts of symptoms as more psychological

and behavioral open cause and appropriate treatment, while mental health professionals saw it as more in the medical domain.

Both specialists tended to view these, as I see it, through sort of an uncertainty spectrum where they knew it wasn't something that they were really accustomed or familiar with treating and they tended to point the finger at the other specialist which obviously creates challenges in health care delivery and confusing messages for the patient.

The slide after those two slides, Post-Deployment Health Concerns. A Force Health Protection Issue only highlights in that confusing circumstance it creates the stress for patients. It can lead to inappropriate health care use. Inappropriate health care use can lead to iatrogenic harm.

Not to mention the fact that many of these symptom syndromes even though we can't explain them necessarily are associated with decrements and functional status and occupational functioning. At least in my own mind, one of the biggest problems associated with this is that in the military it drives a wedge between us and our patient population by decreasing our credibility and trust or decreasing the -- well, really in both directions.

To some degree there is loss of trust in the provider that the patient is telling them the truth about what is driving their symptoms and their visits to the doctor and vice versa. More importantly, there is a loss of faith in the medical system that it will provide an adequate safety net for people in the post-deployment context.

The next slide simply shows that with regard to this uncertainty problem and medically unexplained symptoms that the institute of medicine felt that strategies needed to be implemented. They recommended some specifics which included clinical practice guidelines. And, consistent with the earlier comment, clinical trials to evaluate approaches to medically unexplained symptoms and similar uncertainty situations in clinical care.

The next slide shows -- it is similar to the one that Megan showed earlier which more or less emphasizes that we were designated in 1999 as the Deployment Health Clinical Center to go along with the Research Center and the Surveillance Center.

The next slide shows sort of a concise version of our relatively expansive mission which we have to sort of boil down to really do it. That is to improve post-deployment health care for DOD health

care beneficiaries. I've added in the reserve component here.

Obviously when they're activated they become DOD health care beneficiaries, but one of the things we learned after the Gulf was that often they are outside of the established health care safety net. Policy changes have occurred over time but still that remains an unsolved challenge in terms of health care delivery.

Go to the next slide. The way we are sort of conceptualizing the challenge to some degree is captured in this political cartoon. It says, "We mapped the human genome, mastered artificial intelligence, and unlocked the secrets of the universe. Meaning we've got great technology. If you hit the enter again, "The wheel, though, still needs some work."

It shows the Firestone tire with a little fracture in it. The basic idea being that medicine is a pragmatic science. Even if you've got the world's best technology, which we do, that applying that to real people, and the fact that it's applied by real people, introduces a lot of challenges.

How do we overcome that? The next slide, this is our model sort of what we're trying to do. I

don't think it's a novel model. In fact, it's borrowed from some models that I'll show here in a minute. The idea is that we develop a cadre with clinical experience, which we've done based on previous deployments, most particularly the Gulf War.

We accumulate clinically relevant evidence. As you might imagine, as was said earlier, clinical trials are decidedly in short supply on some of these questions. We are often dealing with policy group recommendations is the highest form of evidence that we have.

The correlation of that evidence into practice guidelines and then systematic efforts to implement those guidelines and evaluation in the form of clinical epidemiologic studies looking at implementation strategies and the effectiveness of those strategies not only on implementation but on health outcomes. Then an ongoing recursive cycle of this approach essentially over and over.

The next slide shows the model of care which we are promoting. This is a model put forward by Mike Von Korff and colleagues from the group Health Cooperative. And to some degree it's countered to what I would describe as sort of authoritarian culture which exist within the military.

That is where medical problems are defined collaboratively between provider and patient. The importance of that problem is negotiated based on its medical importance according to the medical expert in the room and the patient's motivation to overcome it.

Then a continuum of services that involve, probably most important in all of this, sustained active follow-up. More important than necessarily what we do for these folks is often the trust and confidence that we gain in following them over time.

The next slide is a gloss-over slide but it's simply to show that this model of care is based on an institute of medicine model on disability prevention that involves predisposing, precipitating, and what is called here disabling factors or perpetuating factors. And the fact that there are not only biomedical but other factors that impact on ultimate health outcomes.

The next slide highlights a specific aspect of interest that we have in terms of building this model of care, and that is an emphasis on helping clinicians communicate environmental and other health risks better to their patients.

This slide runs through advantages of doing that, one of which I would highlight at the end of the

list there is that if primary care providers are practicing in a consistent way good risk communication with their patients.

Over 90 percent of our beneficiaries see a primary care doc at least once a year so there is the opportunity to have relatively private conversations about risk with someone with a combination of modest technical expertise and good communication training who is still relatively trusted.

If we can overcome some of the clinician motivation, or lack of motivation to communicate some of these risks and variations in skill, we have the potential to have a very positive impact.

Von Korff in the next slide elaborated their approach which is akin to our own approach to promoting this model of care. They suggested guidelines and an emphasis on clinical information systems, performance indicators, and both patient and provider incentives.

A key one is stakeholder involvement, particularly as it relates to post-deployment care and science-based technical assistance, which the next slide shows, at least as we would have it, would be us.

The way our mission breaks down is into

three basic components; health service delivery, health service informatics, education, and communication, and health services research.

The next slide shows that in spite of that very broad mission, we are somewhat limited in our staffing. We're in the mid-40s with regard to staff. We have people split across all three of those missions and administrative people to support them.

Operation Solace is a project that stratles all three areas. That is a response to people with health concerns after the Pentagon attack on September 11th which I'll touch on a little bit more here in a minute.

The next slide shows our mission concept which is essentially that all these services, the service delivery, the education, and the health services research all overlap at the clinical practice guideline. This clinical practice guideline, which is the DODDA Post-Deployment Health Evaluation and management Clinical Practice Guideline is really in the military jargon at the tip of our spear. It drives what we do.

The next slide really transitions us into the guideline which I wanted to say a bit about because it's so central to what we do. The slide

after that really lists contributing agencies. I just want to emphasize here that we're not -- we didn't develop this single handedly and we certainly don't want to be said to be taking all the credit for this. Our task is really to implement this document which took two to three years in development.

The next slide describes a little bit of the background of Clinical Practice Guideline. It fulfills recommendations of two Institute of Medicine panels to develop guidelines for people post-deployment. It was a concept that was collaboratively defined between DOD and VA clinical experts beginning in 1998 and was subsequently briefed to high-level policy people in both DOD and VA.

The next slide shows that this was field tested in three high-deployment sites for six months before it was fielded. It was fielded in the first half of 2002 with "full implementation" in 1 July.

I say quote unquote because anybody who works around guidelines and clinicians knows that it's a constant struggle to distain the implementation of these guidelines. I think that we conceive of it as an ongoing sort of beating of the drums to maintain an emphasis on post-deployment care which arguably has not been highly emphasized in the Department of

Defense in the past.

It currently serves as clinical backbone for post-deployment evaluations in subsequent health care and has really taken the place of, if you will, the comprehensive clinical evaluation program that existed before.

The next slide shows basic features of the guideline. It hinges around a military unique vital sign. That it uses a stepped care framework and has risk communication guidelines. There is web-based clinician support that goes along with it. Unlike the CCEP which was a single evaluation as longitudinal emphasis.

There is data automation features which allow us to mine administrative data to look at the sorts of problems that people are reporting after various and sundry deployments. There's metrics and outcomes monitoring prescribed within the guideline. Of course, the center of excellence involved in implementation which is us.

The next slide just shows the military unique vital sign prescribed in the guideline, "Is your visit related to a deployment?" (yes-no-maybe). This is a patient rather than clinician determination. The patient is asked that. It's a bit like asking

them to rate the severity of their pain which is a recent JACO promoted vital sign.

What we found so far, the concern was that everybody would rush to the table and say their problem was deployment related. We are still trying to learn exactly what it means but less than 1 percent of the people who have been cared for under the guideline say yes to that question which has at least a couple of pragmatic implications.

There is obviously lots of unknowns about the adequacy of that question. One thing we can say for sure is that given that it's a small segment, there's the opportunity to carefully tailor their care.

The other thing to keep in mind is that this is a baseline that has been established so far in relative peace time so what's going to happen after whatever it is that's going to happen here in the next couple of months still remains to be seen.

The next slide highlights the coding that is prescribed within the guideline for people who report a deployment related concern. In other words, a visit that's related to deployment. There's an ICD code and a definition for that code which we're still tweaking to some degree trying to get the administrative

elements to adopt this coding in its entirety and the definition in its entirety.

The next slide shows the stepped approach to risk communication that is prescribed within the guidelines. In simple terms it asks the clinician to make a determination as to whether the patient's problem falls into one of several communication relevant groups and then offers advice on what to do for them and hopefully tools on how to do it.

The next slide shows one of these groups, the asymptomatic patient with health concerns which after the Gulf War represented about 10 percent of people seeking Gulf War related care. These are people who expressed a concern but don't exhibit any illness or describe any discernible symptoms or injury. In that case there is a code for the visit as well as a code for the nature of the problem.

The next slide shows another group on that stepped approach, the group with medically unexplained symptoms. For that there is a code and obviously the employment related business code that goes along with it as a secondary code.

The next slide shows that if someone answered yes to the question and had a clearly identifiable disease, then they would have as their

primary code their usual disease coded followed by the code indicating the fact that this was in conjunction with a deployment related health concern which would allow us to identify that patient as someone who is relating their health problem to the deployment.

The next slide shows a key tool for implementing the guideline. One of the comments that came forward from a DA health care provider as we were developing it was, "How can we know what's wrong with our patients if DOD doesn't tell us?" Whether or not you accept that sort of a comment, it does highlight the fact that there is often much more that we don't know when a person comes back from deployment about exposures than what we do know, particularly if as a health care provider you didn't go on the deployment with the soldier.

We're using the website to help clinicians to identify early information related to health concerns following a deployment. And, quite frankly, to get to them even media information about deployment related health concerns so that at least they can be aware of the concerns and ideas that are out there in the general public and may be driving health care visits.

DR. OSTROFF: Chuck, can I ask you to try to

wrap up in the next minute or two?

COL. ENGEL: Sure. The next slide, again, is another one just highlighting features of PDHealth.mil. The subsequent series of slides talks about spin-off projects from the guideline which sort of highlights it importance as a developmental tool in terms of improving post-deployment health care. It has led to the development of self-help information.

The next slide has -- a couple slides down has a -- it talks about the clinical practice guideline toll free help line for people who are looking for deployment related care or have questions, as well as health care providers.

The next slide highlights the Health-e VOICE project which is a CDC-funded project that uses that stepped approach to risk communication and develops a way of teaching clinicians how to use it.

The next slide after that talks about Operation Solace which I won't go into detail about other than to say this was an effort in which we modified the guideline for implementation in the D.C. area to enhance primary care of people with Pentagon attack related health concerns and anthrax, bioterrorism related health concerns as well as deployment related health concerns.

Next slide just simply shows that we are acutely aware that the guideline is not a finished product. As I said earlier, a lot of the evidence is preliminary that we are using. It does have a life cycle that allows us to revise it. In this coming year we are looking to revise it. We are bringing together the collaborators so we can build on what we've learned so far.

The current challenges to implementing the guideline are adhering to the visit coding, monitoring the metrics, building supporting risk communication tools in an ongoing way. And, probably most important, implementing organizational support strategies for it. There are longer-term challenges which are listed on the next slide that I won't go over to save some time.

The next couple of slides really just talk about a conference that we put on which was aimed at learning more about how to enhance communication about environmental health risks in clinical environments and involve multi-agency collaboration.

The next couple of slides after that discuss various education information products that we've been involved in. We've collaborated with the VA on some world-wide satellite broadcasts, as well as Army

MEDCOM, satellite broadcasts for guidelines and for risk communication and some other things that you can see that are listed in the slides.

The next slide shows health services research. Certainly we are not a research agency per se but we are committed to evidence-based health care. I am a firm believer in the comment that was made earlier that we need to be doing more clinical trials. We need to be doing more intervention studies.

I'm a great admirer of the Co-Op Studies Program within the VA where they are doing multi-center clinical trials. We have a long ways to go for various reasons to being able to do that sort of thing within BOD in the same kind of way. But it's something that I think is out there and the capability that we at least needed to dovetail with the VA and perhaps develop our own capacity for doing clinical trials on relevant questions related to deployment care.

These are our efforts in the research domain. It has involved a lot of blood, sweat, and tears. We have projects funded by a number of agencies, as the next slide shows. In the last fiscal year we published almost 30 scholarly publications. We are currently working with DOD National Quality

Management Program on Special Studies to look at guideline implementation. We are collaborating with VA centers as much as possible with a similar sort of bend.

Our future directions, as the next slide captures, we want to ramp up for the current Southwest Asia deployment. We've been involved in some planning with the Army Surgeon General about what to do there. We are interested in improving guideline implementation, joining the implementation of the guideline to CHCS2 to enhance its implementation.

We are launching -- particularly aimed around the ramping up for the Southwest Asia deployment we're launching guideline consultation teams, two teams that will be going out to various regions and medical centers to improve uptake of the guideline. We are entering into this revision of the guideline.

I think that speaks to most of the more relatively immediate issues. Then, again, I would just come back to the question for the Board which is we're interested in your advice on how clinical epidemiologic methods can be integrated into what we're doing, how we can perpetuate and improve our population health care concept and model.

We're interested in your review of various mission elements and our emphasis on each and whatever analogous civilian sector programs that you think exist and ways of collaborating, particularly with the VA but other federal departments as well and their related centers of excellence.

So that's about it. I think I ran over more time than even Megan.

DR. OSTROFF: Yes, you did, but we certainly appreciate your willingness to get on remotely and it just shows how well you are able to do that, although we would have loved to have had you here in person.

Let me just open it up for the group for questions.

Dr. Cattani.

DR. CATTANI: Yes. Both presentations were really excellent. It seems that recruit screening and post-deployment medical screening are being well looked after. But my question is the missing link seems to be what happens during deployment.

About three meetings ago we had a presentation on immediately pre-deployment screening and records that are kept by those deployed. I remember that there was quite a discrepancy between the records from the different services and how

adequate the actual medical records that were -- even the individuals recording of what they were exposed to or what they experienced during deployment.

Without looking at that system more carefully, it will be difficult to sort out anything post-deployment. My question is is anything being done to enhance surveillance during deployment either in terms of new methodology or improving the current approaches?

COL. ENGEL: I guess my comment in response to that is yes, there are. I'm not the person necessarily who can give you the best summary of that. I think some of the people involved in surveillance, Mark Rubertone's activity and Col. Kelley, Pat Kelley, I think some of those folks are probably better equipped to answer that question than me.

I do know that there has been an aggressive thrust towards environmental monitoring in theater. I think that also only highlights some of the challenges because the instance that I related to you before of the Uzbek situation is an instance where we did our own field environmental monitoring, came up with some things, and then in a good faith effort attempted through local media and so on to inform troops.

What it did was created a good size hubbub

which then turned out with subsequent testing not to pan out. Then we had people who complained of symptoms later based to some degree about concerns that persisted about those exposures and the combination of those concerns and mistrust.

I think the better we get, the more problems we have. Let's put it that way. I think the better we get, the more that it highlights the need to have post-deployment systems in place that involve health care providers and others on how best to communicate the vast array of what we know and health implications of what we know to the service member.

The answers, I think, we are fooling ourselves if we think that they are going to be clear. The answers that we're going to get from surveillance data in theater are going to probably raise as many questions as they will answer. We're going to have to be ready to put our best foot forward.

COL. GARDNER: This is Col. Gardner from Health Affairs. There's a tremendous amount of stuff going on in terms of surveillance in theater. I could discuss it with you if there is time on the program sometime in the next couple of days. We are implementing electronic surveillance. There's deployment, environmental surveillance, and there's

quite a bit of stuff going on. That has not been neglected.

DR. OSTROFF: Bill?

DR. BERG: Yeah, I would like to talk this over with you. This is Bill Berg. I would like to talk this over with you on a break. Could you briefly tell us what, if anything, is being done -- I don't need details -- on surveillance for oil well fires? Saddam has threatened, or at least is reported to have threatened, to prepare to blow up the oil wells.

This was one of the most dramatic and most visible signs of environmental pollution, environmental ill health, at least by attribution, in the Persian Gulf War. It was one of those things that is just so obvious. People concluded that they just had to be sick. One of the criticisms was that nobody had a really good handle on it. Is that possibility specifically being addressed?

COL. ENGEL: Well, as you know, the Army Center for Health Promotion and Preventive Medicine did extensive post-Gulf War studies on those issues and modeling of the plumes and so on. They, therefore, have the capability of doing the same in the future and currently have systems set up to do soil water and air sampling in theater. We try to do

that before we go to places and before we set up base camps, as well as ongoing monitoring during the operation.

There will, of course, be the same type of analysis following the operation. I've been waiting five or six or eight years to get data out of that. We should be able to get data within weeks or months after that.

DR. OSTROFF: Chuck, I have a quick question for you. I noted on your list of deployments that have had these types of difficulties that it didn't include Afghanistan. I'm wondering if that's been a relatively syndrome free deployment. If so, do you have any reasons as to why that might be the case?

COL. ENGEL: Well, I guess it depends on whether you lump Uzbekistan with Afghanistan. The reason the troops are in Uzbekistan is because of operations in Afghanistan. I have not been aware specifically of people complaining of symptoms or syndromes relating to Afghanistan per se, although in talking with folks that have been there, there is certainly a lot of environmental concerns.

There is a range of exposures that people have raised their hand and wondered about. So far I have not heard it as -- let me put it in these terms.

I have not heard it raised as a risk management concern where we had a subset of people who were insisting that they had ailments that were from those exposures.

I just heard about people, you know, relayed their experiences in the various exposures that occurred while they were there. I don't know what to attribute that to. I do think that to some degree this is about an information dissemination issue and a lot of the information disseminates through the veterans network and through the media.

The larger the number of people deployed, the more -- you know, the larger this critical mass becomes in terms of creating a load of information, if you will, that's getting around and causing people to raise concerns. Again, that's not to belittle those concerns. It's just to say that the public's attention and imagination sometimes has to involve a larger rather than smaller number of troops.

I would just call attention to the fact that no matter what happens in the Gulf this time around, we've got close to 200,000 troops over there. I think in a certain respect the cat is already out of the bag even if a shot is never fired.

DR. LEMASTERS: Hi. This is Grace

Lemasters. I was trying to think of how to be responsive to your question about clinical epidemiology. One gap I would see developing here potentially is you said that everyone has asked this question, "Do you think your condition is deployment related?" But if they are -- if they have a condition, let's say, like depression and are assigned an ICD code for depression, it might be related to the deployment like post-traumatic stress.

If there is an ICD code for that but they are not given a deployment code, it seems like there might be some gap, unless there could be a secondary code that says, yes, they have this disease condition, depression, or post- traumatic or whatever, dermatitis, how are you going to solve that ICD code that is given is going to be associated with a deployment exposure like, say, something causing dermatitis so that you'll be able to truly connect the deployment to the condition?

Just one other secondary issue is have you looked at those who said yes, no, or maybe and then being able to say, well, what proportion of the nos are really yes and maybes are yes? That's another whole area. That is sort of a secondary issue that I wanted to bring out.

COL. ENGEL: I guess one broad comment that I would make is that you are highlighting some important health services research related questions that need investigation. As I said earlier, I think in many parts of this guideline there is a distinct shortage of evidence. I think, at least from my own mind, I felt sort of bound to persist just based on the notion that I saw this as a way institutionally of heightening our level of concern about the types of research that needs to be done to improve care in this domain.

I think you are highlighting some of those issues that we are obligated to go forth and do some basic studies looking at the validity of the responses and who, in fact, and what sorts of problems do people have when they endorse the deployment related question.

Another comment that I would make to that, and I wasn't sure that I completely understood your question, but you said we are asking patients if their condition is deployment related. I would say that is not exactly what we are asking. We're asking if their visit is deployment related. I think in some fashion it would be unfair to ask patients to draw that link.

The other reason we sort of side-stepped

that a little bit is that we wanted providers to use it and our concern was it wouldn't pass the smell test, if you will, with a clinician to say we are going to let the patient tell us whether this is deployment related. Instead what we're asking them is whether a concern that this is related to deployment is provoking their visit. Not necessarily whether this condition is definitively related.

A follow-on point is just to say that I don't think for an instant that we think this is going to give us the capacity to make definitive population linkages that are subtle between deployments and health issues. It will, however, particularly in the early going, reduce the need to create highly visible sort of stovepipe types of programs like what came out with the comprehensive clinical evaluation program.

It will give us the capability of gather some administrative data that will allow us to get a fairly gross sense of what kinds of problems people are relating to that is causing them to seek care for their deployment.

It's an initial clinically based surveillance strategy that will provide some gross data. It's certainly not any kind of epidemiologic study. The data will have all the pitfalls, if not

more, of any administrative health care data set.

DR. OSTROFF: Chuck, thanks very much. We're going to have to move on in the interest of time. We, again, certainly appreciate your being willing to give your presentation remotely.

We also very much appreciate Col. Kelley being willing to do the same thing. I will challenge Col. Kelly to try to give his presentation as efficiently as possible since the enchiladas are here. The longer he takes, the longer it will be before we get to out lunch.

COL. KELLEY: I thought I could smell enchiladas. I will aim to get this done in 20 minutes.

Good morning. Again, my name is Col. Pat Kelley. Over the last 18-month period between the spring of 2000 and the fall of 2001 the Institute of Medicine conducted an external evaluation of the DOD Global Emerging Infection Surveillance and Response System, which we for short call DOD-GEIS.

GEIS requested this extensive review by the OIM to help ensure that the program was on target and delivering to the American taxpayer a useful return on investment. The review included site visits to the DOD overseas medical research units, plus meetings

here in the United States for collection and discussion of additional information.

The committee was headed by Dr. Phil Brockman of Emory University and also included either international experts in Global Emerging Infections Surveillance. These experts were drawn from the academic community, from Health Canada, the World Health Organization, and the Caribbean Epidemiology Center.

These state epidemiologists from the State of Maine also was a member of the OIM committee. The review included as one of its recommendations a further annual external review by an appropriate body. This morning in follow-up to Dr. Winkenwerder's request to the AFEB, I would like to fulfill this external evaluation role. I would like to provide some further background on the DOD-GEIS program.

Second slide, please. The DOD-GEIS program can trace it's lineage to this 1992 publication from the Institute of Medicine. Among other things this book highlighted the unique capabilities of DOD to contribute to addressing the threat of microbial threats to the national.

The unique capabilities that were highlighted were specifically the DOD's network of

overseas medical research units. The IOM not only enumerated the value of these labs, but also lamented the fact that in the years just prior to the publication of the report, several of the labs had been closed, specifically labs in Malaysia and Korea. Subsequent to this 1992 IOM report another DOD lab in Brazil was closed in the late 1990s.

Shortly after the 1992 IOM report, both the CDC and the NIH also highlighted DOD's unique potential for contributing to Global Emerging Infection Surveillance through their own planning documents.

Next slide. The recommendations of the IOM, the CDC, and the NIH supported the formal expansion in 1996 of the DOD's missing through the mechanism of a presidential decision directive on emerging infections.

The directive highlighted the weaknesses of the Domestic and International Public Health System and called for the establishment of DOD-GEIS as a centrally coordinated program and encompassing improved preventive health programs and epidemiologic capabilities not only in DOD medical treatment facilities, but also in the overseas lab. The central coordination is managed by a Central Hub located at

the Walter Reed Army Institute of Research and I am the director of that Central Hub.

Next slide. This slide highlights the often misunderstood point that the genesis of the program was not primarily better information for force protection or for use by the military health system, but rather to use DOD scientific assets to achieve a broader national purpose. In that sense you can think of this is somewhat being analogous to the way DOD assets might be used to fight forrest fires or to perform drug interdiction support.

Because of this broader focus, DOD-GEIS is unusually integrated in its activities with other U.S. Government agencies, the World Health Organization, and the International Health Community. The combatant commands such as SOUTHCOM and Pacific command have also been highly supportive of GEIS seeing it as a tool in their international military an humanitarian assistance engagement efforts.

Next slide. To give you a feel for the magnitude of the GEIS program, I would like to share with you this budgetary data showing trends in Core Defense Health Program funding. In this current fiscal year the core budget is $9 million with a $1 million increase programmed for fiscal 04.

As per the instruction of DOD Health Affairs, 65 percent of these funds are directed towards the five Army and Navy overseas medical research units. In subsequent slides I will go a bit more into detail on the various segments of the program.

Next slide. The program has two primary arms. The activities conducted out of the overseas labs are managed by my deputy for overseas lab activities, Commander Randy Culpepper. The Army's labs are located in Thailand and Kenya. The Navy's three overseas labs are located in Egypt, Indonesia, and Peru. These labs are highly capable of multidisciplinary platforms for research and public health surveillance. All together they employ approximately 1,000 individuals most of whom are host country nationals.

The second primary arm of GEIS is executed through various activities conducted within the military health system. Most of the Navy's activities are coordinated by the Naval Health Research Center in San Diego. You heard those described earlier by Dr. Russell.

The Air Force conducts most of its GEIS related activities out of AFIERA and San Antonio.

Army-led initiatives are generally coordinated by my office in the Central Hub at RARE.

Next slide. The Central Hub was created and published as a strategic plan in 1998. This plan was heavily inspired by CDC's own National Emerging Infectious Disease Surveillance and Response Plan published a few years prior.

With the help of a tri-service staff the Central Hub monitors the execution of our strategic plan, reviews and prioritizes annual requests for funding, coordinates funds distribution and the production of annual reports. I believe you have at least one of those that has been delivered to the Board members. We also represent GEIS before numerous military and civilian forums domestically and internationally.

I would like to now highlight briefly the type of surveillance activities conducted out of the overseas labs. As core programs for all overseas labs, GEIS chose surveillance for influenza, drug resistant malaria, drug resistant enteric organisms, and unexplained fevers.

These foci were chosen when the budget was comparatively small and GEIS had to focus on the distinct comparative advantages of the overseas labs.

Certainly malaria and enteric work was historically something the labs were equipped to do but on a smaller scale than desirable.

These were also felt to be militarily relevant. The focus on influenza also reflected a comparative advantage in that the Air Force has for years been operating global influenza surveillance on a smaller scale with notable success.

With the concern over pandemic influenza it seemed that an influenza surveillance program executed out of the overseas labs could be a high-yield activity and it has been.

Next slide. GEIS flue surveillance conducted by both the overseas labs and many military treatment facilities is highlighted on this map. As noted, this has been a rather high-yield activity. For example, the H3N2 Panama strain in the current influenza vaccine was provided to CDC and the FDA from GEIS surveillance conducted in Panama.

In a selection of the H1N1 New Caledonia strain in the current vaccine was based on the fact that the GEIS program executed out of the Lima, Peru lab was the first effort to find this strain in this hemisphere through surveillance on Peruvian naval recruits. This observation persuaded the FDA Advisory

Committee that this New Caledonia strain was spreading globally and, thus, it was recommended for inclusion.

Next slide. GEIS malaria drug resistance surveillance efforts are also providing useful information to malaria drug developers at RARE. In addition, prophylaxis and treatment recommendations have been influenced by information derived from this arm of our program.

As an example, you see here some data from the lab in Lima, Peru. A public health service officer assigned to the GEIS program in Peru was able to conduct a series of in vivo studies in various parts of Peru which illustrated that even within the particular country drug resistance patterns varied to such an extent that different regimes are indicated. In fact, the Peruvian government has now tailored its treatment recommendations for different regions of the country based on this work.

Tracking antibiotic resistance among common enteric organisms is also an important part of the program as illustrated by this example of data, again from the Peru lab. As you can see here, in just seven years resistance among campylobacter to both ciprofloxacin and malidixic acid has increased dramatically. In fact, roughly doubled.

Next slide. In addition to surveillance, the overseas lab arm of GEIS participated in international response directly through support to host countries and indirectly through participation in the World Health Organization's Global Alert and Response Network, or GARN. An illustrative example of the multi-disciplinary, multi-lab resources that can be brought to bear in an international response is illustrated by the next slide which covers the 1997/98 outbreak of Riff Valley Fever in Kenya.

This outbreak involved several hundred human deaths among a pastoral people and the death of tens of thousands of their animals. The Army's Kenya lab is well placed for an immediate response. Both field epidemiologic and entomologic resources were mobilized. An entomologist at the Thailand lab with extensive prior expertise in Riff Valley Fever was also mobilized.

At the time of the outbreak there was no capacity within Kenya for local diagnosis of Riff Valley Fever so a field assay was rapidly established in country by the Navy's lab in Cairo. In addition, since the Army is the only source in the world of human Riff Valley Fever vaccine, we were able to contribute to the response 40 doses of human Riff

Valley Fever vaccine to protect laboratory workers.

A truly exciting extension of the investigation was a GEIS funded partnership with NASA to use satellite remote sensing data to develop a predictive model. This modeling, which GEIS and NASA investigators published in Science Now allows GEIS to post on its website monthly predictive maps that highlight at-risk areas for which Riff Valley Fever animal vaccines can be considered to help prevent the outbreak from being extensively amplified in the animal population.

Next slide. While the overseas lab site of GEIS has had notable successes as outlined by the IOM report, it's been a challenge. Superimposing a public health program on a research infrastructure raised cultural challenges as the business processes and products for surveillance and vaccine or drug development in evaluation differ.

The GEIS program has imposed new stake holders on the lab and has demanded development of new patterns of information dissemination. Methodologies to do global surveillance are evolving and not always accepted and the number of epidemiologists available to execute the program at these labs has been inadequate, though improving. A final challenge has

been the source of authority and the level of response in situations calling for an international response.

Next slide. It became clear as GEIS evolved that DOD could play a key leadership role but that truly global surveillance would require many partners. Some of these partners had to be trained and supported. To this end GEIS has emphasized training of both DOD personnel and foreign national partners as being essential to extending the influence of the program. We have really felt that leveraging our resources is key to capacity and to sustainability.

Next slide. I would just like to share with you an example of the type of leveraging I'm talking about. The GEIS division over the last several years has included a partnership with Taho's Caribbean Epidemiology Center. You can think of CAREC as a mini CDC supporting 21 Caribbean countries that pay membership to support its regional work.

With $700,000 in humanitarian assistance funds from the Atlantic command and the southern command, GEIS has sought to help CAREC establish a model lab-based surveillance network within the Caribbean region based on the Center for Disease Control's Public Health Laboratory Information System Software.

The first step was to provide CAREC with the equipment to establish a website so they could better disseminate surveillance findings. You see the web address listed.

Subsequently 15 national labs were computerized and over 250 epidemiologists and labortorians were trained in how to use the CDC software for hierarchial surveillance.

Currently 11 countries participate actively in tracking enteric illnesses, denge, and HIV. I would note that this model has been replicated over the last several years also with GEIS support in the Andean ridge countries. Most extensively in Peru and across the seven countries of Central America.

Next slide. The Military Health System side of GEIS has focused on filling gaps in DOD's routine surveillance capability. You heard about some of these from the folks out at NHRC earlier this morning.

Up until GEIS funding was provided, though, DOD had no formal mortality surveillance system. GEIS was interested in identifying unexplained deaths that could suggest an emerging infection. We started a project several years ago with Dr. John Gardner to this end.

To create the capability a rapid all-cause

surveillance system was necessary and it's currently managed by the Office of the Armed Forces Medical Examiner at the AFIP.

Another focus of the MHS side of the program has been on improving public health laboratory services in DOD through establishment of a web-based catalog of specialized assays available through DOD reference labs. This in the GEIS agenda for lab-based reporting was formally reviewed and enthusiastically supported by the AFEB several years ago.

A final major focus of the MHS side has been the recognition that there is a stronger mechanism needed for outbreak alert, especially as the threat of bioterrorism to the nondeployed infrastructure came more into focus.

Next slide please. Our focus for improving the MHS alert response has been the development of an innovative surveillance system called ESSENCE, or the Electronic Surveillance System for the Early Notification of Community Based Epidemics.

In its earliest form ESSENCE focused on taking ambulatory primary care data from 104 clinics within a 50 miles radius of the White House grouping the ICD-9 codes into seven sydromic categories suggestive of outbreaks of public health importance.

Then producing daily trend analyses comparing the daily experience with historical data to assess the significance of deviations from expected levels. Subsequent to September 11 ESSENCE was rapidly expanded to over 300 DOD installations world wide. Currently all three services use this mechanism to keep tabs on morbidity experiences.

Next slide. Have the largest system of this type in the world has allowed GEIS to make many interesting observations because significant deviations are noted almost everyday. One of the most interesting phenomena was observed in January of 2002 when at least four training installations almost simultaneously had major outbreaks of gastrointestinal disease. The largest outbreak took place at the Marine Corps Recruit Depo in San Diego and was shown to be due to Norwalk like virus.

Next slide. ESSENCE is funded as both an operational and a research and development project to evaluate a variety of innovative ways of rapidly detecting aberrations in community health. It has been the development philosophy that the most sensitive and effective systems for syndromic surveillance will not segregate the military community from the civilians in their midst or vice versa.

To that end, DARPA funded the ESSENCE 2 project which has been conceptualized as a prototype test bed for a civil military integrated system for the National Capital Region. In partnership with Johns Hopkins and other institutions military ambulatory data is being supplemented not only by data from military pharmacies and nurse hotlines, but also with a variety of complementary data from civilian sources.

Next slide. After being in existence for about five years GEIS has reached adolescence but there are a variety of issues still maturing. Some of these are highlighted here and reflect issues noted elsewhere at the meeting or earlier in this presentation.

The second item on the list, completion of executive agency and the governing DOD directive and instruction, is specifically targeted to address IOM recommendations about the nebulas command and control structure of GEIS that has made it uncertain at times how to deal with a number of management issues.

Sorting out these management issues, which to some extent also affects other aspects of the DOD public health surveillance system, should help address issues that hinder essence from achieving maximum

effectiveness.

Next slide. The IOM review of GEIS offered general recommendations that are summarized here. They clearly felt that the program was worthy of further investment. As noted earlier, GEIS has suffered a bit from not having available for assignment to the overseas labs sufficient experts with training in applied epidemiology.

This has improved over the years both through the allocation of more authorizations for trained preventive medicine physicians and through assistance from the public health service which has assigned people to both several overseas labs and the GEIS Central Hub at RARE.

Reflective of the need to leverage limited U.S. Government resources, the IOM recommended more emphasis on training of DOD personnel and foreign public health personnel. This has been done with an increased emphasis on collaborations with international organizations and other U.S. agencies.

An area in need of continuous emphasis is improved internal and external communication of GEIS findings so that surveillance can truly support timely action. The IOM committee reflecting a healthy skepticism of novel systems such as ESSENCE recommend

that careful evaluation before substantial investments by ESSENCE. The pressure of the times, however, has pushed ESSENCE implementation at a faster pace than might otherwise be justified.

I would note, though, that the vast majority of funding in support of ESSENCE comes from DARPA, not the Defense Health Program. DARPA is an agency which by philosophy is committed to funding high-risk, high-yield projects that would not normally compete well before funding agencies.

Next slide. Another recommendation of the IOM focused on the management issues noted earlier, the challenge for GEIS has been that it is a tri-service project which in its earliest years had close operational management by DOD health affairs with the effect that the authority limits and expectations of the executive agent were never exactly clear.

The ability of the GEIS Central Hub given its unclear status in the DOD hierarchy fostered a disconnect with respect to its responsibility and its authority to do the things needed to fulfill its responsibilities. The growth in the staff of the GEIS Central Hub has fostered increased travel as recommended by the IOM to consult with the field units.

A final major recommendation of the IOM was for a periodic external review. That is the question before the Board today. Given that contracting with the IOM is a very expensive undertaking, it's the hope that a subcommittee of the Board can perform a more limited annual evaluation.

Next slide. Listed here are a few of the issues that probably need to be considered in taking on this request. One is that GEIS is really part of a larger national and international strategy. As such the reviewers need to understand the larger picture to put GEIS in perspective.

Since much of the program is conducted side by side with the Military Infectious Disease Research Program, it's essential that opportunities for productive leveraging and synergies be considered. Likewise it's essential that GEIS not detract from the research mission of the overseas labs.

It goes without elaboration that GEIS should also complement other surveillance activities of the military health system. And the criteria for evaluation also need to be settled.

The last slide. As an ongoing program, some stability of oversight would hopefully keep the program consistently heading in the same direction.

As the committee will discover, the GEIS program is a complex program that goes well beyond what I could present in the last 20 minutes.

To understand the breadth and depth of the effort is going to take a little bit of time. A variety of types of review can be explored any of which should advance the cause. We would appreciate whatever input the Board can provide.

As noted, the Institute of Medicine's 18-month review of the program was extensive and it cost nearly $400,000. We felt that such an investment was justified given the novelty of this mission and the fact that it was budgeted at a total of about $59 million for the period between 2000 and 2001.

If the Board feels it useful, GEIS should be able to develop a modest budget to support travel and other expenses that the Board may incur in supporting the requested review. Thank you very much.

DR. OSTROFF: Not bad, Pat. I think it was 24 minutes. Let me open it up to some comments and questions from the group.

DR. HERBOLD: Pat, this is John Herbold.

COL. KELLEY: Hi, John.

DR. HERBOLD: Do you have as much buy-in from the other federal and international agencies as

you do from DARPA and DOD?

COL. KELLEY: If I heard the question right, do I have as much buy-in from the other federal agencies as we do from DARPA and DOD?

DR. HERBOLD: Yes.

COL. KELLEY: I would say so. Steve Ostroff could comment since he was really I think there at the birth of GEIS. GEIS from its earliest days was heavily coordinated with the work of a wide variety of other federal agencies. But currently, as I noted, we do have, for example, Public Health Service officers that are assigned to the field.

We have an outstanding 06 Captain Frank Mahoney who really runs the program at the Cairo lab. We have Jim Olsen who plays a heavy role in the virus aspect of the Lima, Peru lab. Formerly Trent Rubush, an 06 from the Public Health Service was at the Lima lab running our malaria drug resistance work.

We have a veterinarian named Claire Witt assigned to the Central Hub who coordinates antibiotic resistance veterinarian West Nile surveillance for us. I think there is definitely buy-in from a variety of parts of the Government. I think it's probably going to increase in the years to come, too. I have been working, for example, with Secretary Thompson's

office.

They have funding now to establish a large program for international surveillance that should complement the GEIS program. It will be primarily run out of the WHO and the CDC but I think we are looking for many possibilities of cross-fertilization and leveraging.

DR. CATTANI: Jackie Cattani. I have a question about ESSENCE 2. I remember when we had a presentation on ESSENCE 1 that it was not exactly real time in the sense that it was three to seven days before the syndromes were coated and the ICD codes were included in each of the individual syndromes.

Is ESSENCE 2 more real time than that or could you give us a figure on how quickly this surveillance system can alert to some unusual aberrations in the data?

COL. KELLEY: You bring up an interesting point. When the last briefing was given you are correct that some of the delays were noted. Since that last briefing we have been able to study basically risk factors for delayed reporting.

There are many records that are reported within 24 hours and some take as long as two weeks. I think the main problem with reporting is one that

would be addressed by some of the administrative issues that are being worked through right now to try to organize surveillance at a higher level in the DOD hierarchy.

People report data based on the standards that are set for reporting. I suspect that with ESSENCE somewhat buried down in the DOD hierarchy we've had a lot of trouble getting the visibility it needs to have policies promulgated that require rapid reporting.

Many of the reporters don't even know that they are part of a bioterrorism surveillance system. You have some MTFs that just are able to report very fast. We sometimes have data, as I mentioned, within 12 hours of a clinic closing and others it drags out. Even within a clinic sometimes you get some records within a day and other records trickle in over a week.

Our hope is that by helping to sort out some of the higher level command and control issues, when we have problems that I think could be solved by better promulgation of policy, we can take advantage of that.

Now, ESSENCE 2 specifically is also faster for several reasons. One is that it uses a variety of sources of data, one of which now is incorporating DOD

pharmacy data which we are able to get access to within three and a half seconds of when a prescription is issued. We have been doing a number of studies that show very nicely how prescribing patterns correlate with morbidity patterns.

We also feel that the nurse hotline data, we'll be able to get that faster. I don't know if that exactly answers your question but we have greater understandings now of what that problem is and what the solutions are. The solutions we do feel are practical and partly can result from a more effective integration of the system into the official DOD policy for bioterrorism surveillance.

DR. OSTROFF: Pat, I have one quick question for you and then I think we'll have to break for lunch. As you probably know, there is going to be a new IOM report that is coming out on Emerging Infectious Diseases next month. This is the 10-year update of the original report that you mentioned at the beginning of your presentation. Did you participate in the development of that report and have input into the content?

COL. KELLEY: We participated in a number of ways. The DOD contributed $100,000 to that new report. Half of it came from the GEIS program and

half of it from the Military Infectious Disease Program. When that report was -- when the writing of it was kicked off we were invited to give a briefing to the committee specifically to outline what the original report had accomplished with respect to our agency's response to emerging infections. I did participate and give that briefing.

I have also maintained contact with the committee members, a number of whom were involved with writing the GEIS IOM evaluation. For example, Ret. Col. Don Burke, I believe, has been serving on both -- served on our committee and also on the rewrite committee for the book you mentioned.

DR. OSTROFF: Other comments? Let's just take two quick ones.

DR. GARDNER: Yes. Thank you. This is Pierce Gardner working at the Fogarty Center. Your work obviously has implications for defense, but also for the greater issues now in global health which include a security and diplomatic efforts to improve the health.

I was particularly interested in your linking of ecology, I guess, to satellite to Riff Valley Fever risk. That seemed to be a particularly interesting and useful venture. I would love to learn

more about it. Perhaps I need a different setting.

COL. KELLEY: We'd be happy to fill you in. In fact, we were able to extend that model to Yemen about 16 months ago when Riff Valley Fever crossed out of Africa into Yemen and Saudi Arabia. I think someone asked earlier whether other federal agencies -- I think it was Dr. Herbold -- whether other federal agencies are partnering with us and supporting us. This is an example of how NASA, for example, is partnering with us to do something that I'm not sure either of us could do very well alone.

DR. OSTROFF: Last question from Dr. Cline.

DR. CLINE: Pat, Barney Cline. Just for clarification, in your third to the last line on the major recommendations of the IOM program review it lists the bottom periodic external review every few years to ensure appropriate focus and goals. I thought I understood you to say annual review. Perhaps I misunderstood but could you clarify?

COL. KELLEY: I did say annual and they said it could be every few years. I think it is certainly something that is negotiable depending on how extensive an effort looks like would be feasible.

We do provide an annual report and I think a copy has been distributed to you, hopefully both the

short version and the longer 400-page CD-ROM or hardcopy version. I would be open to whatever insights you might be able to find the time to provide.

DR. OSTROFF: Thanks very much. Once again, we appreciate you taking the time to be able to give the presentation. We'll have further discussions this afternoon.

If there are no additional issues to raise, why don't we go ahead and break for lunch and try to make it back very promptly at 1:30.

(Whereupon, at 12:22 p.m. off the record for lunch to reconvene at 1:30 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:30 p.m.

DR. OSTROFF: Let's go ahead and get started

so we don't find ourselves getting behind in the afternoon session.

Our first presentation of the afternoon will be from Maj. Serrano which is the ethics briefing which is a requirement on an annual basis. We appreciate also Maj. Serrano taking the effort to be able to do this remotely. Hopefully we will do as well as we did in the morning session.

MAJ. SERRANO: Good afternoon to the Board. Can you all hear me?

DR. OSTROFF: Yes.

MAJ. SERRANO: Okay. Thank you. I appreciate the opportunity to do this remotely. It is bad enough usually to teach ethics to people's faces so this is even more difficult. However, what I did is I put my dog up next to me here so instead of looking at the computer, I'm just watching the dog and if she tilts her head, I'm just going to presume one or more people are not getting the material and I'll try to cover that a little more carefully.

The first thing I would like to do is welcome the new Board members. For those of you who are present and have not had this it is a requirement to have initial ethics training when you are first appointed as a member of the Board. For the rest of

you, again, welcome.

I would like to go to the next slide, please. I've got on that second slide my contact information. I know that you are just convening after lunch so this is going to be a particularly difficult portion. If you head hits the desk from here on in, please keep a copy of this slide and you may ask further questions or ethical issues of me directly. Or you can pass them through Dr. Riddle who I am in contact with quite often.

I would also like to say that if you have any questions throughout the presentation, just scream or something so that I can stop talking and listen to your question. Another option would be just to pass those questions to Dr. Riddle and I will try to respond to the Board in writing at some later time.

Let's go to the next slide. The agenda of things I'm going to cover today. I'm going to first talk about some of the actual regulatory requirements and go over the sources of ethics with you and the principles of ethical conduct.

Then I'll get into the meat of the training which is the conflict of interest. I also have a couple of other issues I would like to cover, teaching, speaking, and writing. I've had several

questions on this in the past how it applies to special Government employees.

The last bullet, other issues, I'm going to cover a couple of things. First of all, I'm going to cover a previous question of the Board which dealt with the emoluments clause of the constitution. Then I'm also going to just cover the OGE Form 450, Confidential Financial Disclosure Report, just briefly.

I know you don't have copies of that form but I'm just going to go over just a couple of common issues that come up so that the next time you are required to fill those out, you keep those in the back of your head. You will be able to fill out the form without so many questions. I know the form is very confusing at times. After that we'll just leave it open for some questions.

Next slide, please. The things I'm going to cover are all based on the bullets that you see now. First of all, the principles of ethical conduct are 14 principles that are promulgated by the President of the United States. First, Jimmie Carter in the late '70s and later President George Bush the first.

Those 14 principles are the basis for all of our ethics laws. There are statutes that implement

some of those principles and there are other regulations by the Office of Government Ethics. The bottom line is if you keep going back to those 14 principles of ethical conduct, which you'll see in a moment. You will never go wrong.

In fact, without knowing any of the detailed regulations, if you read one of those principles and you get a funny feeling in your stomach, you probably should go with your stomach feeling and ask a question or give me a call about whatever issue it is that's bothering you. A lot of ethics law and regulation is very much common sense as opposed to other types of law. If it doesn't feel right, it probably isn't.

The second source of ethical law are the Standards of Conduct. I've put the website up there if you are interested in seeing that particular publication. It is a collection of regulations that's promulgated at 5 Code of Federal Regulations 2635. There are a whole series of things which take the principles of ethical conduct and break them down into details so you can be exactly -- you can go into detail and parce the actual rules to see whether or not something is permitted.

Once we get into that type of issues, if there are questions, once again, go back to the first

rule which is please give me a call and I can go through it with you because sometimes we can find an exception or a loophole that will permit you to do what you want to do. Other times it's not possible but we need to delve into that particular document in depth to find that out.

The third source which I put up there is the Joint Ethic Regulation. The JER is a Department of Defense publication and it supplements the Standards of Conduct and covers certain areas that the Standards of Conduct don't particularly cover and make them applicable to Department of Defense employees.

We do use the Joint Ethic Regulation a lot of times in deal with certain things like receipt of gifts and other types of similar issues. But often times we can answer all of our questions going right back to the Standards of Conduct.

Finally, I put up the criminal code, 18 USC Sections 201 to 209. Those are the conflict of interest statutes that I'm going to be talking about in a little bit. Those statutes are criminal and if you happen to break one of them, you are subject to potential prosecution by the Department of Justice.

This is just my little editorial comment. This is not the views of the Army or the Department of

Defense. Ordinarily it has to be a fairly high level of issue before they decide to prosecute you.

I'm not advocating breaking the rules but if you happen to slip up accidentally or you are attempting to follow an ethics opinion and you just make a mistake, technically you are subject to prosecution. In reality they are probably not going to come after you.

The next slide, please. The next few slides, actually, are the principles of ethical conduct. I'm not going to cover them in depth. In fact, I'm just going to scroll through them quickly and just mention a couple of highlights and main themes that surround all the rules.

First of all, a lot of times I get phone calls from folks that have ethics questions. The first two things out of their mouths is, No. 1, I don't work in contracts and, No. 2, I'm very honest. I appreciate that. I'm glad that everybody who calls me up is very honest. However, the fact is that the rules and the principles really take your specific honesty out of the picture and they essentially prohibit -- strictly prohibit certain conduct.

The reason for that is that it prevents us from having to look at a particular person's honesty.

Yes, most everybody who works in the Government is honest but some people aren't and if all the ethics folks had to do investigations to determine honesty, I wouldn't get much business done obviously. Keep that in mind.

I understand that especially members of this Board are probably approve reproach when we start talking about honesty, but simply your particular honesty is not relevant when it comes to the rules. It's just not a part of the analysis.

Let's skip through the principles now. You can go ahead and peruse those at your leisure. I'm sure you'll get into those at the next break. Let's go right now to the slide which begins with conflict of interest.

The conflict of interest statutes deal with fairly diverse topics but the main topics are to prevent the actual and/or appearance of some of kind of taint of Government officials by some third party. Whether you are employed by the third party, whether you get a bribe from the third party, or whether they are paying you something on the side, or any of those situations can lead to an actual conflict, or appearance of a conflict even if there is no actual one.

As special Government employees you have to be especially vigilant because you don't do this Government business full-time. You do this obviously a few times a year and then you go back to your normal work. I have read a lot of your CDs and I see the diverse practices out there.

If's very, very -- it's incumbent upon you to be very, very vigilant about things you're doing for the Government and how that might impact things that you're doing in the outside world. Some of you have one or two different things that you do mainly and there are several others which I read. I frankly don't know when you find time to eat or relax because you do a ton of things. Just keep that in mind.

Let's go to the next slide, please. The main conflict of interest statute that we are concerned about with regard to members of the Board is 18 USC Section 208. I put up the legalese on the slide for you. The main thing -- we are going to cover these in a little bit of depth but the main thing I want to focus with you is the very last bullet.

Basically you can't take any kind of official action in any particular matter in which you might have a financial interest. This goes back to

the comment I made earlier regarding contracts. A lot of people say, "I don't do contracts." It certainly encompasses contracts but it's not limited to those.

If you are employed by a particular third party; if you are, in fact, seeking employment with a third party; if you own stock in a third party; if you spouse or minor children work for the third party, the statue essentially imputes the financial interest to you. It would be as if you own stock or worked for a particular third party.

Let's go to the next slide, please. The next slide covers the conflict of interest elements. Couple of pointers on this. I will get back to the point about the financial interest in a moment. First of all, may not participate is relatively self explanatory.

By personally and substantially the statute relates to matters -- let me back up please. When we talk about personally and substantially we're not talking about kind of a broad concept of the issue here. We're talking about something that would be event based.

When you look at whether or not you are participating personally and substantially in a particular matter, we have to look at a specific

transaction. I'll just give you an example that may not apply directly to the Board but you will get the point from it.

If, for example, I am a colonel and I am an acquisition Corps officer and I am personally working on the widget project, trying to get the widgets approved for production for the Army, my particular work with the widget would be something very specific. I would be prohibited from getting out of the army and coming back as a contractor working on widgets.

However, if I as a colonel merely were talking about the very general ideas of classes of widgets that we might want to use some day but we never get down to exactly specific widgets, that would not be considered a particular matter. I could get out of the Army and come back and work on this broad-based widget white theory without any kind of conflict.

Similarly, if I were just supervising somebody who is working on the widget project but I was not personally involved in it, that would not constitute a personal and substantial involvement in the widget project. Now, there are other limitations for me as a supervisor which I'm not going to get into right now. Instead of a lifetime ban you have a two-

year ban.

The bottom line is you have to actually get your hands dirty when you're talking about personal and substantial participation. It can't be you prepared the slides. It can't be some, you know, passing out of files from one person to another. You actually have to be involved in the project.

The fourth element, direct and predictable effect, and here it is somewhat legal-like analysis. It is an approximate cause type analysis, and that is is the effect that you're going to get to your financial interest direct and predictable.

Let me give you an example here. If my spouse works for McDonnell Douglas and she works in the bookkeeping department and she is paid a salaried wage, we participates in a 401K plan that is just based strictly as a matching contribution of non-McDonnell Douglas stock into her plan.

I am in the Government service and I'm working on a project in selecting a contractor, one of those contractors being McDonnell Douglas. In a case like that, if I were to decline the contract of McDonnell Douglas or, in fact, grant them a contract or order the contract for McDonnell Douglas, my wife is still going to get paid the same amount of salary

whether I give the contract or not. She is still going to get matching contributions to her 401K and it has no effect on that. In that example there would be no direct and predictable effect.

On the other hand, if the area I was contracting with she was a -- it was a smaller company and she was an employee for that company and it meant sink or swim for that particular company, that obviously would have more of a direct and predictable effect. You have to look at that as well.

Finally, employees financial interest doesn't only include your own personal interest but it also includes your spouse and your minor children. What we normally see there is employment of the spouse and/or stock owned by the spouse or minor children. For example, your spouse or minor children own McDonnell Douglas stock, that ownership interest would be impeded to you for purposes of analysis.

Next slide, please. Okay. The next slide deals with what exactly do we do if we have a conflict of interest. First of all, the fact that you don't write down "I am disqualified" on a piece of paper doesn't really mean much because you are automatically disqualified. There are ways we can memorialize the disqualification by writing it down, and I'll talk to

you about that in a moment.

The bottom line is if you have one of these financial interests, you are disqualified from taking any official action with regard to that company. Now, there are a couple different things you can do as opposed to disqualification.

You can be reassigned. That is, your supervisor can say, "We want you to work on X, Y, and Z projects but you're not going to be working on the widget project at all." You can change your duties, very similar obviously, but for purposes of the Board, very difficult obviously.

Divestiture. You can divest yourself of your interest so if you own Boeing stock and your company -- let me use a Board example. Let's say you own Merck stock and the Board is dealing with some issue involving Merck, you could choose to divest yourself of your stock as opposed to disqualifying yourself from Board action.

Now, divestiture isn't something that is done very often for a lot of reasons. Some people have substantial holdings. They don't want to go through buying and selling stock every time they change jobs depending on what job it is they have. Also, if you don't do it properly and go through the

Office of Government Ethics, you can end up paying capital gains on the sale of your stock.

If you are interested in divesting yourself of an interest, please contact our office or Dr. Riddle ahead of time and I can help you with that. If, in fact, it is an issue and, in fact, you wish to divest yourself of your stock, I can get a certificate of divestiture from the office of Government Ethics which essentially lets you defer your capital gains on the sale of your stock.

Finally, there are some waivers available to you. Those waivers allow you to take official action even though you have a financial interest. The most common types of waivers are regulatory and they normally deal with stock. The current limitation on stock ownership is $15,000.

If you own $15,000 or less on a particular stock and a matter comes before the Board involving that particular company in which you hold the stock, if you own $15,000 or less, you are free to go ahead and take special action on that matter despite the fact that you own the stock.

If you own more than $15,000, then once again, please call me up or please correspond with Dr. Riddle and we will go through a further analysis there

in trouble shooting that.

Finally, there are individual waivers that can be granted even if you don't fit into the regulatory waiver scheme. They are not very common. In fact, they are rather rare and, in fact, they have to go all the way up to the Office of Government Ethics for approval. We don't seek those types of individual waivers very often. If it is in your best interest to do so and the best interest of the Board, get with me and we'll see what we can do.

I'm not feeling the love here. Is everybody doing all right in there?

DR. OSTROFF: We're fine.

MAJ. SERRANO: Okay. Moving on then. Conflict of interest, appearance of conflicts. Next slide. Despite the fact that you may not have an actual conflict of interest, you may have what is an appearance of conflict of interest. The appearance issues are just as deadly to the proper operation of the Government agency. If you have outside parties looking in and it seems like things are fishy, that can be just as damaging as if things are actually fishy.

The test of that is would a reasonable person in possession of the relevant facts see

anything wrong. It covers virtually any appearances of impropriety as opposed to actual impropriety. The conflicts cover interest of people who you have a colored relationship.

Let's go to the next slide. I would like to parce that a little bit. First of all, the impartiality of not whether or not it would look bad on the Washington Post. You have to actually go back to that reasonable person test, which I mentioned. If you are a supervisor who is, in fact, a decision maker in this case, looks at all the facts and determines that there is no conflict, then you have no conflict and you can essentially get a waiver from your supervisor. But it is the supervisor who has to grant that waiver.

Next slide. The types of covered relationships. We talked already about spouse and minor children and those are not appearance issues. Those are actual issues. If you have other types of relationships, though, other than familial relationships, that can also cause appearance problems.

For example, one of the bullets talks about relatives. If your Uncle Bob, who you are very close to, is the CEO of General Dynamics and you are the

decision maker for buying a new Air Force engine for the F-16, then you probably have an appearance of conflict issue if not an actual conflict issue.

Now, on the other hand, if Uncle Bob in that same scenario and you've been estranged from Uncle Bob and you've never -- you haven't talked to him in 30 years, the supervisor who has to take a look at those facts sees that you have not, in fact, talked to this particular relative for essentially your whole adult life and then there would be no appearance of conflict. That's why it's so important to know all of the facts.

If you belong to a particular organization or you work as an officer, director in the previous year and got out from that organization and moved on, then you also would have a potential covered relationship. We actually had a case here in the office with some individuals who came into the Office of the Chief Army Reserve and who were essentially vice presidents for some major corporations.

They had some appearance of conflict issues and we had to resolve those because even though they didn't work for the company anymore, it would look bad if they were awarding contracts to the former company.

Next slide, please. In the case of the

appearance of conflicts issues, the analysis is exactly the same. However, there are no regulatory waivers. There's no $15,000 stock exemption or any of those. The only thing you are left with is the individual waiver and that essentially goes to your supervisor for a decision on whether or not there is a conflict. If you have questions about that or you need to toot that around, please, again, through Dr. Riddle get hold of me and we can resolve those issues.

Next slide, please. I would like to just take a moment and see if there are any questions regarding conflict of interest. I've not covered them all but I've covered the ones that are most likely to apply.

DR. POLAND: Tom Greg Poland. As I recall, this does not pertain to things that we don't really have control over like mutual funds or things that your employer might be involved in that you have no reason to know about. Am I correct about that?

MAJ. SERRANO: Yes. The question is whether you have conflicts with things such as mutual funds or things that your employer does that you have no control over. That is essentially correct, sir.

The particular case that you mentioned, mutual funds, in fact, mutual funds, for those of you

who when you are filling out your OGE Form 450 and you write down Fidelity Magellan and you wonder why I need the name of the fund there, most mutual funds do not create a conflict because they are so diverse and they are held by so many people.

In fact, you have no control over what assets the fund buys theirselves that there really isn't a conflict as to any particular issue. The one exception, which is rather rare, would be what we call a sector mutual fund.

In a sector fund you're talking about like a biomedical fund or communications fund or computer fund or something of that nature where the fund holdings are all concentrated in a particular business or particular area. In that case we do have to do a conflict analysis. For the vast majority of mutual funds, there is no conflict.

Again, I agree if the company that you're talking about is doing something in another division or another section that doesn't impact you, you have no control over it and so on, that would be absolutely true. There would not be a conflict and I just go back to my hypothetical about a spouse working for a different division of a large corporation. Obviously any action you take is going to have no impact on

their job.

Any other questions? Okay. There being no questions, I would like to cover the teaching, speaking, and writing very briefly. The main gist of teaching speaking and writing is that you can go back to one of the 14 principles. An employee will not use his or her public office for private gain. The main co-provision here, 5 CFR 2635.807 says that you can't use your official Government duties to make money on the side.

Next slide, please. I would like to -- I have the actual CFR code listed out in the next couple of slides. What I would like to point out, though, is how to recognize this. If on the Board you are working with the Cucamunga virus and you are an expert in the Cucamunga virus and you are asked to give a presentation at some kind of conference on that particular virus, if you are already an expert on the Cucamunga virus, then there is no problem with making money and giving a speech on it. The fact that it just happens to be part of Board business is not entirely relevant.

The problem would be if some particular agency wants to find out exactly how is the Armed Forces Epi. Board dealing with the Cucamunga virus.

Something like that because it is a specific Board issue is not due to your expertise. It has exactly to do with the job of the Board. Things of that nature you would not be permitted to make money in speaking.

Now, there are some other things. I would like to go to the next slide, please. I would like to just focus on the bottom bullet there. There are special exceptions for special Government employees. In fact, if you just look up to the previous bullet, there are three dashes there. The bottom two dashes deals with any ongoing or announced policy program or operation of the agency or non-career employees, general subject matters.

Special Government employees can speak within those areas and not violate the rule. The only limitation you would have would be the first bullet which is any matter to which the employee presently is assigned or to which the employee has been assigned during the previous one-year period.

If you are talking about a specific Board issue and someone wants to pay you to come and talk about that, that would be a prohibition. The other two listed prohibitions there for most other Government employees do not apply to SGEs.

My advice here is 807 can get complicated.

It's very obtuse when you read it. If you have any questions in this area, please give me a call and we can talk about it. For the most part, though, if you just ask to speak within your discipline and they are not wanting to know exactly what the specific Board actions are going to be in this area, you can go ahead and speak and you can go ahead and get paid for that and you will not run afoul of this particular rule.

Do you have any questions on the teaching, speaking, writing?

Okay. The next issue then. Go to the next slide, please. I would like to talk about the Emolument Clause of the constitution because I don't recall who asked the question at the previous meeting in September. I do offer my apologies that I never offered anything in writing to you regarding this issue. I did research it extensively.

The essence of the Emoluments Clause is that you can't be anyone who is holding an office of profit or trust for the Government, can't receive any kind of title, gift, payment, things of that nature, from a foreign state.

Next slide, please. Now, the question came up in this case exactly under what conditions are special Government employees going to occupy offices

of profit or trust. In fact, there was an actual Office of Government Ethics discussion at one of our meetings for an entire hour about this issue.

To make a long story short, the Office of Special Counsel and Office of Legal Counsel has applied this clause to special Government employees and some of the factors that they've used are those factors in the third bullet; frequency of the meetings, whether or not you are being compensated, whether or not you've taken an oath, and whether you have access to classified information.

I talked to Dr. Riddle previously about this and he told me that, in fact, the Board does deal in classified information from time to time. Based on that it was my opinion, and is my opinion, that the Emoluments Clause does, in fact, apply to members of the Board as long as you are under an appointment. Not necessarily just in session but throughout the term of your employment.

Now, this is my understanding as I understand the Board right now. If this creates an issue with people, if you need to talk to me about this in your particular case and figure out whether it applies, or, in fact, if you believe that my understanding of the Board operation is incorrect,

feel free to contact me and I can go through this issue again.

I know this can be a sensitive issue. Please contact me and we'll talk about this more. As far as I understand it, the clause does apply to members of the Board while you are under employment. Any questions or discussions about that?

DR. POLAND: Does that include honorary degrees?

MAJ. SERRANO: I beg your pardon? I couldn't hear that.

DR. POLAND: Does it apply to honorary degrees?

MAJ. SERRANO: The question is whether this applies to an honorary degree. I don't have the ability to answer that right now. I would have to get back to you. My sense of it is that it would not apply to an honorary degree because, in fact, it's honorary. I can't say that for certain so that's one thing I'll take down.

DR. OSTROFF: Are there other questions for Maj. Serrano?

DR. POLAND: I've got one other. Is information still classified once it's in the public domain?

MAJ. SERRANO: The question is whether or not information is classified once it's in the public domain. Legally I would say no only because generally speaking if something is still classified by definition, it's not in the public domain. However, practically speaking, I don't know how that would apply. Could you give me an example of that?

DR. POLAND: The Board has heard classified information only a week later to read about the same information in the New York Times.

MAJ. SERRANO: Okay. I don't have a good answer for you. I mean, the technical answer is it's still classified. The fact that the Times found out about it doesn't necessarily mean it's classified. I think the test applies more to whether or not you, in fact, deal with it on specific issues and not necessarily what has happened to actual information.

COL. RIDDLE: Yeah. I'm not an expert but I spent several years in the intelligence community and I have seen in movies, on TV compartmented intelligence and reference to the particular compartments which are and remain classified information. What they told me in relation to that is I can't divulge my knowing that that compartment exist and the information within that compartment, even

though it may have been on a movie. That doesn't prohibit me from talking about what was on the movie or, in this instance, what was in the newspaper. You just can't add credibility or infer that you have knowledge of that in a realm of information outside of public information. Now, that was my understanding, Tom.

MAJ. SERRANO: Okay, sir. In fact, I think that's just a little bit -- that's kind of separate from what the test was here on whether or not an office of profit or trust is occupied. The fact is the Board does deal with classified information. On that basis alone without looking at any particular cases, I would apply the Emoluments Clause to the Board members because of that issue.

I just wanted to add one more thing to the discussion here regarding the OGE Form 450. You may find this helpful. For those of you who are just coming on board and are having to fill out 450s, this may be immediately helpful to you. For those of you who filled them out yearly, well, pack up the notes in a box some place and then maybe they will help you later on at the end of this year.

Just a couple of things. First of all, the first section of the 450 deals with assets. The

section asks you to list your assets. One of the most common mistakes that I get -- in fact, the Board is actually pretty good about this but it is just the population in general that I get 450s from -- it is not helpful for me to get a 450 that has listed, for example, an asset the Charles Schwab brokerage account because I can't do conflict of interest analysis if I don't know what's in the account. Then you are filling out the form, please don't write brokerage account. You have to list the individual assets in the account.

When you list your mutual funds you don't have to list all the assets in the fund. You just have to list Fidelity Magellan or USAA Aggressive Growth or those types of things. I don't really care exactly what's in the fund itself unless it's a sector fund and, in that case, I'll know from the title. If it's like Fidelity Communications or something like that, I can go and do the further research on it.

The other areas the 450 asks for on the second page is it asks for certain information that often times is duplicated. It asks for any kind of past employment or future employment or future agreements, in which case most of you, if not all of you, are going to list whatever it is you do in the

real world aside from the Board duties.

Then it may also ask you to list something else aside from the employment that might have to do with that particular company's retirement plan or something like that. Yes, the form can be annoying because you have to list information several times. Please take a look at what the form is asking for in that areas.

I would like to conclude on that note. I'm sorry I couldn't be there in person. I'm looking for a trip to somewhere a little bit warmer. I would have looked forward to actually doing the big room again but I'll have to catch the Board at the next meeting.

Thank you very much for your time and if there are no questions, once again, please call me if you have any issues whatsoever, or at least get hold of Dr. Riddle and I'll be happy to get back to you as soon as I can.

DR. OSTROFF: Maj. Serrano, thanks very much. It's always a pleasure to hear from a lawyer who finishes his presentation early.

Let me open it up to the Board to see if there are any other comments or questions that they wish to bring to your attention. I'll just say that we appreciate that you are doing this for us and your

willingness to always be available to speak about any potential issues that might come up.

I see no hands so we'll move on to our next session. Once again, thanks very much for your willingness to get on the phone. I know sometimes it's not easy to do that and we'll look forward to seeing you in person next year.

MAJ. SERRANO: Thanks very much, sir. I hope the Board has a fruitful session.

DR. OSTROFF: Unfortunately it's raining here.

MAJ. SERRANO: Oh, okay. I hope you at least get it over with then.

DR. OSTROFF: Thank you very much.

MAJ. SERRANO: Take care.

DR. OSTROFF: We'll move on to the next session. I believe that Col. Gunzenhauser is on the phone.

COL. GUNZENHAUSER: I am.

DR. OSTROFF: Great. He's going to introduce this particular topic. This is a topic that has come before the Board in the past and has now -- there's been a great deal of progress over the last several years so there's additional information to be discussed. I'll let Jeff introduce the topic and then

we'll move on to the presentation.

COL. GUNZENHAUSER: Okay. Thank you very much. Can you hear me okay?

DR. OSTROFF: Absolutely.

COL. GUNZENHAUSER: Okay. Great. I guess in your booklet there should be a memorandum from Ms. Ellen Embrey. The subject is QuantiFERON - TB's Application in the U.S. Military.

DR. OSTROFF: Right. Unfortunately, we don't have the booklets either but we'll take your word for it.

COL. GUNZENHAUSER: Okay. And there's four slides that I've got to introduce the question and I presume you are able to see those?

DR. OSTROFF: Yes.

COL. GUNZENHAUSER: Okay. The first slide is how should the U.S. military use this newly licensed test. As a little bit of background, everybody knows that tuberculosis rates in the U.S. are very low, less than 10 per 100,000 per year. As such tuberculosis really is not a threat to the health of trainees, globalizing populations, or garrison base troops as it was back in the early 20th century.

On the left, TB is a threat to the health of deployed personnel and it's among numerous health

issues that emerge as potential deployment related concerns.

Tuberculin test testing remains the test used by DOD in diagnosing latent tuberculosis infection. Several aspects of this test that many of you know including variability in administration and reaction assessment, as well as the 48/72 hour follow-up reading remain cumbersome aspects of a test, especially in relation to deployments.

A blood assay whose acquisition requires just a single clinical encounter and whose analysis resolves to within laboratory quality control would be a very attractive alternative that could solve many of the administrative burdens of the standard skin test.

Let's move on to the second slide. QuantiFERON TB test, also known as QFT, measures a compound in a cell mediated immunity to microbacteria and tuberculosis. The test is based on a quantification of the interferon gamma released from sensitized lymposites in whole blood which is incubated overnight with purified protein derivative and control antigens and MTB.

As a test QFT, as it's called, requires phlebotomy. It can be accomplished on a single patient visit. It assesses responses to multiple

antigens simultaneously. Also it doesn't boost anninestic immune responses. It's definitely less subject to reader bias and error than the conventional tuberculin skin test.

Next slide. The Board last reviewed issues concern risk-based tuberculosis screen policies and new technologies in February of 2000 and published recommendations in May of that year. At that time the Board reviewed information available on a whole blood assay.

Your comments at that time were that the assay holds great promise as an alternative method for TB screening of military personnel, but that a number of questions needed to be answered before it's general could be considered and that the test should be licensed by the Food and Drug Administration.

Since that time the assay has been licensed by the FDA and guidelines were recently published by the Centers for Disease Control for use of the test in diagnosing latent tuberculosis infection.

Also, recently the manufacturer of the assay provided a report to the Joint Preventive Medicine Policy Group which provides answers to many of the questions which the Board outlined in its May 2000 recommendations.

The last slide. December of 2002 the CDC released guidelines for using the QFT for diagnosing LTBI. These guidelines indicate that the test can be of use among certain populations who are at increased risk for LTBI including recent immigrants from high-prevalence countries, injection drug users, residents and employees of prisons and jails, and health care workers who after their pre-employment assessment are considered at increased risk.

While the guidelines discourage the use of any diagnostic test for latent tuberculosis infection among populations who are at low risk for infection, certain exceptions to this general rule were outlined including the use among certain population groups for surveillance purposes or where cases of active infectious TB might result in extensive transmission.

Military personnel were specifically listed among those to whom this exception might apply. With this in mind per Ms. Embrey's request, the Board is asked to review and provide comment on the report and additional research submitted to the Joint Preventive Medicine Policy Group and to provide recommendations on QuantiFERON - TB's application in the U.S. military. That concludes my introduction.

DR. OSTROFF: Thanks, Jeff. Let me just ask

if there are any questions before we move into the next presentation.

Our next presenter will be Dr. Jerry Mazurek who's from the Division of Tuberculosis Elimination at CDC. He's going to -- I guess you were involved in actually writing the recommendations that were published in December and he's going to give us an update on the science behind this.

DR. MAZUREK: Thank you. Can everyone hear me? I appreciate this Board's interest in the work we've been doing in our efforts to improve TB diagnostics and this opportunity to speak to the Armed Forces Epidemiological Board.

I think Dr. Gunzenhauser has actually done a marvelous job of introducing the QuantiFERON. Many of the Slides that I have I think we will go through quite rapidly.

Next slide, please. Basically the plan for the talk was to explain what the QuantiFERON test abbreviated QFT is. To explain why we think that a new test for tuberculosis is needed and to relate how the QuantiFERON test is actually performed and interpreted.

To actually examine some of the potential advantages and disadvantages of the test; and review

some results from significant clinical trials using the test. Finally, to describe the CDC suggestions for using this new test as was recently published in the MMWR.

The QuantiFERON TB assay is a whole blood interferon gamma assay for the detection of mycobacterium tuberculosis infection. Measurement of gamma interferon is a reasonable approach since this cytakine is a marker of cell mediated immune response. TST is also a measure of cell mediated immune response, it measures a different component of this response and, therefore, the tests are not actually the same.

The next slide, please. A new test is felt to be needed because the tuberculin skin test has been our only immunologic test for tuberculosis infection and the only test for latent TB infection.

While the tuberculin skin test has been used extensively for over 100 years, there are numerous limitations to its use. The test actually requires injection of foreign proteins and subsequent measurement of the response generated. Variations in the way the test is applied and measured results in considerable inaccuracies.

Prior BCG vaccination exposure to non-

tuberculous mycobacteria can cause false/positive skin test results because these organisms share many of the antigens that are contained within tuberculosis. Injection of the PPD, the tuberculin for tuberculin skin testing, can generate positive results subsequently through boosting.

Next slide, please. The QuantiFERON TB test is performed by collecting at least four milliliters of blood, mixing it with heparin, and then dividing that blood into four wells and a 24-well cell culture plate. Three drops of saline as a negative control, TB PPD, Avian PPD, or mitogen are added to the different wells. The blood is then incubated for 16 to 24 hours at 37 degrees centigrade.

During this time sensitized lymphocytes produce gamma interferon. The blood is then -- the amount of gamma interferon in the blood is then measured using ELISA reader.

Next slide, please. The measurement and interpretation of the QuantiFERON test is generally done automatically using the ELISA reader and an attached computer. The ELISA reader measures the optical density in each of the wells and in accompanying wells containing standard amounts of gamma interferon.

The computer converts the optical density to concentration of gamma interferon and calculates an interpretation for the test for each subject tested. It reports results as being negative for tuberculosis infection, positive for mycobacterium tuberculosis infection, conditionally positive for mycobacterium tuberculosis infection, or indeterminate.

Next slide, please. This slide is a simplified depiction of results that can be obtained from the QuantiFERON TB assay. Specific cut-offs used in interpreting the test can be found in the test package insert.

The first line represents what one might see when the test is negative. There is considerable quantities of gamma interferon produced in response to the mitogen antigen, while minimal gamma interferon is produced in response to the other antigens. The QuantiFERON TB test is also interpreted as negative if there is a significantly greater production of gamma interferon in response to the Avian PPD then the tuberculin PPD.

The third line on the slide depicts the results of when the test is interpreted as positive in that there is considerable gamma interferon produced in response to the mitogen, and in response to the

tuberculin PPD. The amount produced in response to the tuberculin PPD is larger than that produced by Avian PPD.

For the QuantiFERON test to be interpreted as positive, the amount of gamma interferon produced in response to tuberculin should be equal to or greater than 30 percent that produced by the mitogen.

For conditionally positive gamma interferon results, the amount of gamma interferon produced in response to tuberculin is in the range of 15 to 30 percent of that produced by the mitogen.

Finally, the last line on the slide shows what might happen if the results were indeterminate from the test. Generally there's minimal production of gamma interferon in response to the mitogen which is included as a positive control.

Next slide, please. This slide demonstrates characteristics of the QuantiFERON test and allows comparison to the tuberculin skin test. The QuantiFERON TB test is an in vitro assay which allows multiple antigens to be evaluated simultaneously including negative and positive control.

There's no injection of foreign proteins and subsequently no boosting of subsequent tests that are done. The results can be obtained with one patient

visit. There's minimal inner-reader variability and results from the test can be obtained within one day. The biggest drawback of this test is that the blood must be processed within 12 hours of collection prior to the lymphocytes starting to obtuse or to die.

Next slide, please. Streeton and others assess the QuantiFERON sensitivity and specificity using tuberculin skin test as the gold standard. In that study a test was considered positive for tuberculosis infection if the tuberculin response was greater than or equal to 15 percent.

In their study the specificity of the QuantiFERON test was estimated to be 98 percent in 417 TST negative subjects with no identified risk for tuberculosis infection. The sensitivity of the QuantiFERON test was estimated to be 90 percent in 182 TST positive subjects.

Next slide, please. Because of known limitations in the tuberculin skin test we evaluated the QuantiFERON test without assuming TST to be a gold standard. We compared QuantiFERON and TST in subjects grouped by risk of TB infection and looked for factors associated with discordance in the test results.

We included people that were at low risk for tuberculosis infection, people that were at high risk

for tuberculosis infection due to contact with someone with TB, residents in a congregate setting in which tuberculosis was more common and other situations that increased their risk of TB. Immigrant was also a common reason for inclusion in that category.

We also looked at TB suspects who had received less than six weeks of therapy for their tuberculosis and look at individuals who had completed tuberculosis therapy for culture confirmed TB within the prior two years.

Next slide, please. What we found was good overall agreement between the tuberculin skin test and the QuantiFERON test with 84 percent agreement. The kappa value for this measurement was 0.61. This kappa value, or similar kappa value slightly lower was actually found when we compared tuberculin skin test with Aplesol on one arm and tuberculin skin cells with Tubersol on the other arm.

Factors associated with discordance between the TST and the QuantiFERON test in our study included prior BCG, evidence of non-tuberculous mycobacterial immune reactivity, the site where the tuberculin skin test was applied as to the enrollment site, the study site, not the arm or where it was actually placed, and prior treatment of tuberculosis.

Next slide, please. Using multi-variant logistic regression we found BCG vaccinated people had TST positive QuantiFERON negative type discordance 6.5 times more often than non-vaccinated people. People with strong avian PPD responses by QuantiFERON had TST positive QuantiFERON negative responses 2.5 times more often than those without evidence of NTM reactivity. Finally, some sites had significantly more TST positive QuantiFERON negative discordance than others.

Next slide, please. This slide allows one to look at the effect of BCG vaccination on concordance. What this slide shows is that individuals that were BCG vaccinated were much more likely to have a positive TST but negative QuantiFERON response than individuals that were not vaccinated in that the individuals in the BCG vaccinated group had TST positive, QuantiFERON negative discordance 23.3 percent of the time compared to 4.8 percent for those in the unvaccinated group.

The agreement between the two tests was significantly less for the BCG vaccinated individuals at 70.1 percent compared to the unvaccinated group in which the agreement was 88 percent.

Next slide, please. This slide allows one to examine the effect of non-tuberculous mycobacteria

on the QuantiFERON TST concordance. Basically of the 81 individuals in the high-risk group and low-risk combined who had positive TST or negative QuantiFERON results 18 percent of them had evidence of non-tuberculous mycobacterial reactivity suggesting that the positive TST was the result of cross-reactivity to the non-TM that they had previously probably been exposed to.

Next slide, please. This slide allows us to examine the effect of the site of enrollment on TST and QuantiFERON discordance. And from this you've looked at the previous slide at the effect of site on this type of discordance, the TST positive QuantiFERON negative discordance.

But what this slide allows us to do is see that those sites that had the greatest TST positive QuantiFERON negative discordance such as site D had less TST negative QuantiFERON positive discordance suggesting that some sites were actually over-estimating the size or over-reading the tuberculin skin test.

The only factor found to be significantly associated with TST negative QuantiFERON positive discordance was enrollment at site C. We then looked at the actual readings at the various sites and

through basically measured the frequency with which each reading was made and found that at the sites with the greatest discrepancy in their TST QuantiFERON results had a tendency to have greater digit preference. They had a tendency to read the tuberculin skin test at 10 and 15 millimeters more often than readings on either side of that measurement.

Next slide, please. This slide allows us to examine the effect of tuberculosis treatment on the test results. We assess sensitivity in people with culture confirmed TB by enrolling TB suspects who had received up to six weeks of therapy and in people who had completed their therapy for TB in the prior two years.

In retrospect these people were not good candidates for assessing sensitivity in that we and others have found the treatment rapidly increases their TST responsiveness and decreases their gamma interferon production.

For example, Hook and colleagues reported an increase in the TST sensitivity from 80 percent prior to treatment to 95 percent after two weeks of treatment. Eleanor first described the discovery that gamma interferon responds to decreases with treatment.

Others have subsequently suggested following the gamma interferon response with treatment to assess treatment success.

In our study most of the suspects had received greater than four weeks of therapy for their tuberculosis. In our study TST sensitivity increased from 93 to 95 percent while QuantiFERON sensitivity dropped from 82 percent to 64 percent.

Next slide, please. We estimated specificity in '98 people considered to be at low risk for tuberculosis infection. Assuming that none of these individuals were infected, QuantiFERON and TST specificity was 98 percent. Because few low-risk subjects were enrolled in the CDC study we have relied on other studies for estimating specificity when developing the guidelines for using the QuantiFERON TB test.

Next slide, please. Keep and others actually assessed the specificity of the QuantiFERON test in Navy recruits and found that the QuantiFERON in TST agreed 98 percent of the time.

Assuming that none of the recruits were infected with QuantiFERON, specificity was 98 percent for the QuantiFERON test and 99 percent for the tuberculin skin test in recruits who had the lowest

risk of tuberculosis infection. For recruits from areas of the United States where tuberculosis rates exceeded 10 per 100,000, the specificity of both tests was 98 percent.

Next slide, please. Using the information described we developed guidelines for using the QuantiFERON test with the following testing goals in mind. We wanted to identify those who would benefit from treatment for LTBI. We wanted to increase completion of LTBI testing and to increase the accuracy of the LTBI detection.

Next slide. At the time that the CDC guidelines were written there was inadequate data to support the use of QuantiFERON in TB suspects and in populations at increased risk of progressing to active tuberculosis. These groups would be people that were HIV infected are severely compromised through other mechanisms.

Next slide, please. When testing those at increased risk of LTBI either the tuberculin skin test of the QuantiFERON test may be used in screening these individuals. Examples of people that have an increased risk of LTBI include immigrants, injection drug users, people in congregate settings with increased risk of infection including prisons, jails,

homeless shelters, and such.

Less stringent cutoffs are used in defining positive results for both the TST and the QuantiFERON test in these individuals. A tuberculin response greater than 15 percent is considered positive for the QuantiFERON test as compared to a TST being interpreted as positive when induration is greater than or equal to 10 millimeters.

Treatment for latent tuberculosis infection should be considered if the QuantiFERON test or the tuberculin skin test is positive. Treatment is generally not recommended if either test are negative. Confirmation of positive QFT results is an option and may be done because the QuantiFERON does not induce boosting.

Next slide, please. When testing those at low risk for latent tuberculosis infection, either the tuberculin skin test or the QuantiFERON test may be used. Examples of these people include most military personnel, hospital staff, and health care workers whose risk of prior exposures to tuberculosis is low. It also includes people who are receiving pre-employment or pre-enrollment screening for latent tuberculosis infection.

We believe that stringent cutoffs should be

used in defining positive results such that positive results for QuantiFERON would be when the tuberculin response was greater than or equal to 30 percent as compared to the positive tuberculin skin test results being when they were greater than or equal to 15 millimeters of induration.

Positive QFT results should be confirmed before treating for latent tuberculosis infection. No treatment is warranted if the QuantiFERON test or the tuberculin skin test is negative. We believe that the test that latent tuberculosis infection is most likely to be present when both the TST and the QuantiFERON rest are positive. By using both tests we believe that we can decrease the inappropriate treatment for latent tuberculosis infection.

Inclusion, the QuantiFERON TB test appears to be an acceptable alternative to the tuberculin skin test for determining latent tuberculosis infection in populations encompassing active duty personnel. Thank you.

DR. OSTROFF: Thanks very much. Let me open it up to the group for questions.

DR. POLAND: I didn't understand one point back a couple slides ago when you said the QFT greater than 15 or greater than 30 percent. Is that related

to the control?

DR. MAZUREK: That would be related to the response to the amount of QuantiFERON being produced in response to tuberculin PPD. If that response is in this equivocal area of 15 to 30 percent, the amount of gamma interferon produced by the mitogen, it would be considered conditionally positive and that would be reported out and the clinician if they identify risks associated with tuberculosis would consider the person to be infected with tuberculosis. That's kind of like the 10 to 15 equivocal range in interpreting tuberculin skin test results.

DR. GARDNER: This certainly looks like an improvement. It gets around a lot of observer error. One question of cost. Another would be in someone who does get a booster response to tuberculin skin test, is that also reflected in positivity with this test as well?

DR. MAZUREK: In our prior study we tried to assess that and asked that people who had discorded results return to have both tests repeated. Only 18 percent of the people that were candidates for having that done returned. We didn't feel that we had adequate information to really comment to say that it did boost.

In looking back at those few people that were retested, the majority of them had evidence of either no change or boosting of their QuantiFERON response in parallel to that of the tuberculin skin test. The short answer is, yes. TST can boost the QuantiFERON result.

DR. GARDNER: What about the cost?

DR. MAZUREK: I'm going to leave that, I think, to the next speaker who actually will be Jim Rothel who represents Cellestis, the manufacturer of that test.

DR. POLAND: A couple other questions. Do we know anything about the performance of the assay in subjects that have T-cell defects like HIV infected persons?

DR. MAZUREK: We are starting studies in such people. There was one paper written by Converse who looked at HIV infected people for who prior tuberculin skin test results were available. What they found was that of those people who had positive results in the past, the QuantiFERON was actually more sensitive than the tuberculin skin test.

DR. GARDNER: But wouldn't you have expected these folks to have problems responding to mitogen and ending up in your immediate group?

DR. MAZUREK: Yes. That has not been thoroughly tested but a situation in which you would have a decrease in the mitogen response would be in individuals who had very few lymphocytes to actually respond. In general, it seems that as long as your lymphocyte count is greater than 200, the QuantiFERON test seems to be pretty reliable and give you results comparable to what we find in this assay comparing the TST QuantiFERON. Below that is a problem.

DR. POLAND: My last question is do we know how much variability there is in the assay?

DR. MAZUREK: Again, from person to person and from test to test I will actually ask Jim Rothel to address that question, too, because I think the company has actually done reproducibility studies which was not part of the CDC studies but we did look at them. We were comfortable.

DR. GRAY: This is Greg Gray. I'm looking at your slide here for those at low risk. You just told us that there may be a boosting effect. That is, if you do the skin test first and you were to confirm that the QFT you might see a boosting effect. Yet your slide recommends almost a serial examination in that way.

DR. MAZUREK: And so our recommendations and

that of the FDA are that you not apply or draw a QuantiFERON test after applying the TST. The period which you should wait is one year according to those guidelines. It is acceptable to do the QuantiFERON test because it doesn't induce boosting of the tuberculin skin test so the corollary is okay.

It's okay to test with QuantiFERON and then test with TST. The one exception to that is if in the surveillance program in which their TST was negative and their first QuantiFERON test is negative, then it is acceptable actually and you can use that QuantiFERON test in a period of less than 12 months.

DR. GRAY: Thank you.

DR. OSTROFF: Dr. Cline, do you have a question?

DR. CLINE: No.

DR. ALEXANDER: I have a question. I have a question about treatment taking your algorithm out. I apologize because I haven't been in the TB world for a long time, but as I recall the prophylactic treatment management with INH was really complicated. We had a lot of treatment failures. We had a lot of complications from the prophylactic treatment. What are the implications of the QFT on this, if any?

DR. MAZUREK: Well, I think that if you

actually use the algorithm as we have described it in our recommendations that there will be fewer people requiring treatment for latent tuberculosis infection. I believe there will be fewer inappropriate prescriptions for INH so that hopefully you will be able to concentrate on those people that most use that medicine.

In the same regard you will actually be able to identify people with one visit hopefully that need to be treated if they are at high risk. I believe it will actually I believe improve your chances of adequately treating these people. Some people have a tendency to believe their skin test when they don't believe the tuberculin skin test because they know BCG affects. They have been told since they were babies, "I've had a BCG and vaccination. The skin test doesn't mean anything."

DR. ALEXANDER: True.

DR. MAZUREK: That has not been assessed in a scientific manner yet.

DR. OSTROFF: Dr. Patrick.

DR. PATRICK: The lab test has to be done within 12 hours. Is that right?

DR. MAZUREK: Yes.

DR. PATRICK: How is the specimen handled?

Are there special requirements with respect to handling that?

DR. MAZUREK: The blood is drawn into a green top heparin containing tube. It's mixed and then it's held at room temperature and carried to the laboratory where it's processed within that 12-hour window.

DR. PATRICK: And what's are you envisioning? Are you envisioning that this laboratory capacity would be available fairly approximate to the locations that this would be done?

DR. MAZUREK: In general, yes.

DR. OSTROFF: Why don't we -- I'm sorry. Bill.

DR. BERG: Bill Berg. I run a public health department. I have patients who are referred to me because they've had a TST sometimes for good reasons and sometimes for not so good reasons. What I'm hearing you say is regardless if they've had a TST there's nothing to be gained by adding a QFT.

DR. MAZUREK: That's correct. I don't believe at this time it's a reasonable use of the QuantiFERON test to confirm results of the tuberculin skin test.

DR. BERG: On the other hand --

DR. MAZUREK: Some situations you do confirm a positive TST with a TST and you do that not particularly through CDC guidelines or recommendations. Sometimes you find that tuberculin skin test is negative. Under those circumstances you may elect not to treat the person. Then it comes down to clinical judgment. Maybe we should use that at the onset and not repeat the test.

DR. BERG: The other side of it is if somebody shows up and says, "I was told to get a TB test at the health department," and I assess them at low risk or high risk, then QFT would be appropriate and may even help me sort out those who are not to be treated.

DR. MAZUREK: I believe that's correct.

DR. BERG: Thank you.

DR. OSTROFF: Thanks. Why don't we move on to the next presentation. Beforehand I'll turn it over to Col. Riddle.

COL. RIDDLE: We need to get a hand count for those that are going to dinner tonight. It's the Monte Vista Fire Station, a super menu, super place to eat. Spouses are also welcome. Hold your hand up.

DR. GRAY: Two for spouses.

COL. RIDDLE: Okay. Directions are over

here on the table if you're going to drive yourself. Importantly remember the number 3.1 miles because once you turn left off Wyoming it's 3.1 miles up to the restaurant. Otherwise, we'll all meet over at the lobby of Kirtland Inn at 6:20 and we'll carpool.

DR. OSTROFF: Thanks. let's move on to the next presentation which is Dr. Jim Rothel from Cellestis. He's the Chief Scientific Officer and Cellestis is the company that developed the QFT test.

DR. ROTHEL: Thank you for inviting me here. Apologies for the Australian accent. I hope you can understand me. I think after two talks ago about ethics, I probably should disclose, which has already been disclosed, that I do actually work for the company that makes this test.

Next slide, please. This is a slide with the comments from the last time we presented which was early 2000. I think, as has already been mentioned, some comments came out that the QFT holds great promise. TB screening in the military was important was decided from that meeting.

There were a number of issues that I felt needed some more information before they could recommend its use. QuantiFERON needed FDA approval and it's never been done, as you have heard. This

question, "Will QuantiFERON identify more recruits as positive?" I'll address that in a minute but the answer is no.

They would like more QuantiFERON data. We'll provide that in a minute. Reproducibility was a big issue and we had to present the FDA with a large amount of reproducibility data for FDA approval so I'll show you some of that in a minute.

Cost analysis was provided to Jiff and Peak on use in the military. These last two questions were raised at that AFEB meeting but they were basically questions that needed to be answered by the military themselves. I'm not sure if they have been or not.

Next slide, please. So a brief summary of developments. FDA approval received. CDC recommendations were published in December last year. Great Lakes study that Dr. Mazurek just talked about and CDC studied on. Also a study completed by Walter Reed Army Institute of Research in Kenya has been completed.

There are a number of other clinical studies going around the world. I think about 14 at the moment. I'll show you data from a couple of those studies that give us more confidence in its use.

So Jerry -- Dr. Mazurek I should call him,

or Commander Mazurek. I'm not sure what's politically correct in this setting -- did a study conducted by Lt. Col. Lisa Keep at Great Lakes Navy Station for around 1,500 recruits that didn't really have a respect for TB exposure as per the CDC guidelines.

The slide you saw before that broke it into very low and a little bit of risk. I've lumped them all in because none of them really have a risk factor as per the guidelines. If you look at them all combined the specificity of TST is 98.5 and 97.8.

This also assumes that none of those people truly were infected for TB. There's a possibility that some of them were. At best that is an under estimate of both tests of specificity.

So with the FDA approved cut-off for low-risk individuals and the CDC recommendation as published in the MMWR of confirming a positive QuantiFERON response with the TST before treating, what are the implications of that?

I think it's already been mentioned that those with a positive QuantiFERON and a positive TST are more likely to truly have latent TB infection. I'll show you a little bit of data in a minute to suggest that is true as well.

If we use those criteria as suggested by the

FDA and the CDC, only four of the 1,500 or so people or .27 percent of those recruits that we studied would have warranted treatment for latent TB infection. Under the current practice just using the TST it would have been 1.5 percent of them would have been treated.

I think the answer from this is using both tests we're probably treating those more appropriate that warrant treatment and we're not treating a whole lot of people and exposing them to possible risk of infecting RNH for nine months or so.

This is another way of representing the data from the CDC study. Here I've referring to those individuals that have high risk which are really the ones we ought to look at if we're looking at a test for latent TB screening.

What we have here with this triangle are those who tested QuantiFERON positive. These are positive just to the TST and these are positive just to QuantiFERON. These triangles are actually proportional in size.

Next slide. So what do we know? These people no one is worried about. These people we're not worried about but it's the ones with discordance result. What do we know about them? We know from the analysis, the discordance analysis performed from the

CDC study and published in JAMA that we can account for a large number of these that are TST positive QuantiFERON negative or reactivity due to non-tuberculous mycobacteria BCG vaccination and the digit preference that was spoken about in the previous talk.

There were no real factors that we could find to account for these individuals that are QuantiFERON positive but TST negative. The question raised at the last AFEB meeting was are these people with the TST positive QuantiFERON negative likely to go on to develop active TB.

Next slide. Well, I think the answer to that is highly unlikely because QuantiFERON is wholly sensitive, wholly specific. It generally agrees fairly well with the TST and we can account for many of those TST positive QuantiFERON negative responses by looking at factors such as NTM and BCG and digit preference.

I think the best information we have, except we don't have a gold standard for latent TB infection. We can't prove a person has latent TB. It comes from the animal model.

Let me have the next slide. The best animal model that I'm aware of, and I think it's accepted now, is tuberculous in cattle. It's where the skin

test was originally developed and it's where QuantiFERON was originally developed in cattle.

The immune response of the cattle is very similar to that of humans. A strong CMO response. Strong QuantiFERON response. Most infected cattle don't go out from TB. They develop a latent infection very similar to humans.

Next slide, please. This is a summary from a very large study that we performed many years ago with the Bovine test. A marked similarity to the previous diagram you saw for the human data. I should say this time these three triangles are in proportion and this one isn't because there are 6,000 animals in the study we did.

The discordance rate compared to the positives, the animals that were positive to both tests, the discordance right here remarkably similar to what we saw for the human data. There is a big difference here. We had a gold standard in cattle.

Go to the next slide. The gold standard was culture. We could kill them all and we performed a detailed necropsy looking for gross TB lesions. We didn't find TB lesions. We didn't find TB lesions. We collected 26 different lympnodes from these animals and cultured them individually in the laboratory. We

were finding the organism wherever it was.

Next slide, please. Using this gold standard what was the answer? For those that were positive to both tests 87 percent of them were found to be truly infected. That goes back to what I was saying before. You get much more confidence if they are positive to both tests.

Next slide. For those that are negative to both tests, again it was only .1 percent were found to be infected of necropsy. Again, this gives us more confidence.

Next one. For TST positive QuantiFERON negative surprisingly only 4 percent or two of the 53 animals in that group were found to be positive so a very large false positive rate in this triangle here.

Next one. For those who were just positive to QuantiFERON but TST negative, 55 percent of them were found to be culture positive. Again, those animals were missed by the skin test.

We have actual figures. The sensitivity of the TST in that large study was 65.5 percent compared to 93.6 percent for the bovine equivalent of the QuantiFERON assay.

Next slide. What is the sensitivity for active TB disease? Dr. Mazurek's talk demonstrated

that we didn't from the CDC study get true data on the sensitivity of either the TST or the QuantiFERON test because treatment does affect the response to both of those tests.

Most people estimate the sensitivity of the TST using data from people who have received some treatment. The literature is full of those estimates. They are just about all over estimates because it's well known in the literature, and Dr. Mazurek talked about it, that many people who have a negative skin test at the time are presenting with active TB. Following treatment and nutrition they rapidly within two weeks can develop a positive response.

There's a problem with the CDC study and some studies that have been published from that same CDC data. Especially the substudy, the Balek paper that you may have read. They made a totally incorrect assumption that people with past treated TB are equivalent to those with latent TB infection. We really don't know the answer so we have done a study in Japan.

Next slide. In this study we found -- we tested 112 patients with culture confirmed and tuberculosis infection prior to them receiving any treatment. We found the sensitivity of QuantiFERON

was 82 percent. It keeps coming back to around 82 percent but this time without the effect of treatment of TST and using duration cutoff with only 66 percent sensitive.

I think this data is pretty solid evidence that the true sensitivity of the TST is quite low for active TB and QuantiFERON is 80 percent or better. And for those who like seeing it graphically, this is the same thing.

We've also just completed a study in Italy where there was a lady who went in the hospital to give birth and in the maternity ward she was found to have drug resistant TB and she had exposed 76 other mothers and health care workers. We compared QuantiFERON with the TST in this setting.

I've stated here the QuantiFERON was correlated with the length of exposure. This P value for life somewhat but definitely a solid trend towards being a significant correlation with the length of exposure to the index case and the possibility of being positive.

TST was not correlated in this same situation but both tests were highly correlated with the mums or the health care workers having prior evidence or prior risk of being infected with TB such

as coming from USSR or having worked in a TB unit or things like that. Highly significant.

I think the summation from this study, which the data is still being finally analyzed and hopefully will be published in the not-too-distant future, the QuantiFERON responses are consistent with degree of exposure. Again, it gives us more confidence that the test is doing what we hoped it would do.

Next slide. We were asked at AFEB last time what is the reproducibility of the QuantiFERON test and we were asked again today. Here are some performance characteristics of the test. Limited protection of ELISA 1.5 units per mil in the linear range. Probably not that interesting but this is what we want to get into.

The blood culture stick is highly reproducible with a correlation coefficient between duplicate and triplicate wells of .95. We look at the ELISA itself which measures the gamma interferon component both within plate and between plate variation. It's less than 10 percent CV. Again, good standards, the diagnostic tests.

I think this bottom line is probably the most important one to be interested in. It's between sites and between operators. Again, the ICC

interclass correlation coefficient is .95 showing very good reproducibility. I think the next slide shows some data on that.

This is one of the studies we performed where we collected duplicate blood samples from 50 individuals. Sent one blood sample to one lab and another blood sample to another lab. Forty-four were positive for both, five were negative for both sides and there was one discordant result. That gives us an agreement of 98 percent and the ICC of .94.

We presented this data to the FDA. They asked us for a little bit more on this so we went back and did another study with 50 people at three sites and found exactly the same answer. It's very reproducible.

Probably another good question is the reproducibility of an individual's response over time. In this instance we tested 36 people every two weeks for six time points. Some didn't make it for all the time points. We can see here is that the percentage of human response or the tuberculin response versus the time points.

You can see that these people were O- and below the dotted line cutoff, which you probably can't see. People who were negative remained negative.

People who were positive remained positive. There were a few people as with any biological test that had a response that went from positive to negative.

Overall the reproducibility of the test had a ICC of .84 showing very good reproducibility. I would love to see that same data for the skin test. I think it would be much worst but you can't do it obviously because the skin test boosts the subsequent test.

There are some logistic issues with both tests. With the TST you need to return to have the induration measured on your arm between 48 and 72 hours later. Many people don't. I know in Cook County Jail we thought prisoners would come back but they only get to read 30 percent of their skin tests because they can't find them in the jail or some such thing. Rather surprising.

In the military I remember from the last study the compliance rate actually measuring TST was also not very good in the military. It's a major problem and costly. Personnel time losses are high and this is a major problem with the cost of the skin test. Many people perceive the skin test as cheap but if I asked you what was the cost of the reagent skin test as far as the overall cost it's about 1.5 percent

of the total cost.

A recent paper coming out from Randall Reed in Denver estimated the minimum cost of a TST as being $37 in a public health setting up to $350 at some hospitals. That's not a cheap a test as people perceive. A lot of that is due to personnel time cost.

In a health care worker setting you are paying for the person being tested at the time. Same in the military. Three days to result and you cannot repeat because the results boost.

QuantiFERON TB, we have this problem where you have to get the blood through a laboratory and have a process within 12 hours of being collected from the person. In some settings that's a major problem. In most military settings I think it's probably not a major problem. It requires laboratory. Again, hopefully not a major issue.

Next slide. Getting to the end, why test for TB in the U.S. military? I think the last AFEB meeting came up to the conclusion that it was important to do so but why? The incidence of active TB is very low.

I think I'm correct in stating there is an increasing number of foreign-born people entering the

U.S. military. I'm definitely sure I'm correct with this. There's increase of operations in high-risk settings. In the next slide we just talk a little bit about that.

I think there is a history of some outbreaks being very serious in the U.S. military. This one I think most of you recall on the USS Wasp in the late 1990s where a case of TB was found on that boat in the Atlantic and it ended up with one or two boats being pulled out of the Atlantic and coming back home just because of tuberculosis. That highlights the possible importance of the disease.

Next slide, please. Here is a map of the world showing the TB rates as published by WHO from 1999, I believe, or 2000. Basically the darker the color the worse it is. At any rate, I'm putting this up here just to remind you the troops from here or people from here are joining the military. Some people from here are joining the military is one thing.

The troops from here are now serving in parts of the world where TB is a major, major problem. Where am I? I think that's Afghanistan there. It's got the highest rate in the world of TB. Iraq and that area also very high. South Korea over here very

high rate. Areas where I am aware that there's U.S. military the TB rates are exceedingly high. Those people are at risk of getting infected.

Next slide. Nearly last. I've got three slides to summarize what I see as the benefits of QuantiFERON for the U.S. military. For the medical practice it's an objective and controlled test. It's controlled in the laboratory, it's controlled in the blood culture stage and the ELISA stage. The TST is about the most objective test we've ever heard of trying to measure a bump on someone's arm. That's very imprecise and I think the medical literature will attest to that.

Controls for reactivity to non-tuberculous mycobacteria. It appears to be less effective by BCG vaccination than the skin test. I think the extensive data from cattle and the recent data we got from culture confirmed TB patients shows it's more sensitive than the skin test.

Logistic issues, it's only a single patient visit. You only need to see the person once to get a blood sample out of them. You don't need to rely on them coming back two or three days later to have the bump read. Therefore, there's a reduced labor burden. I think this single patient visit could be built into

times when you are collecting a blood sample from military personnel for other testing such as HIV or whatever testing is done in the military.

Important point, the data is captured electronically. From the last AFEB meeting I remember there was a major problem if people had converted their skin test because record keeping was very poor for skin test results. With QuantiFERON system the data is interpreted electronically and you get an electronic database which can be saved for a source later.

Less incorrect treatment for latent TB. If we adopt the CDC guidelines we'll be treating less people and those that are more appropriate to receive the treatment. It's cost effective. The study definitely shows that and we'll talk more about that in a minute if you like.

The very last slide. Overall it should lead to more service personnel having a TB test result. Many of them you don't get one for at the moment. The detection of those with active TB who are the real critical ones who are going to spread the disease on further. The latent ones are very important, too, because they may develop active TB in the future.

More accurate detection of latent TB and

fewer personnel on latent TB therapy which will be a big savings cost wise if you're not chasing up 500 people. You're only chasing up 100 people to make them comply with the therapy.

I think that is probably enough.

DR. OSTROFF: Thank you very much. Let me open it up for questions. I have a couple of questions for you. Based on your experience, and I know it's sometimes difficult to know exactly when people were exposed, but in terms of the optimal time to use this test after potentially someone has been exposed because a lot of the discussions discerning testing in the past have been, for instance, after deployments. What is the time frame for when the test should be run after someone has been exposed? Is it a couple of weeks? Is it months? Is it --

DR. ROTHEL: The short answer is that's fairly difficult to determine in people. The CDC study that is currently running is trying to do that at the moment, testing people at one month past exposure and then three months. Hopefully we will get some data on that. That's going to take some time.

I think the best evidence comes from cattle. Again, a lovely model where we infect the animals so we know the day they got TB. In cattle they are

invariably positive within two to four weeks after infection. All of them are positive by four weeks after infection. Most of them are positive at two weeks. The skin test seems to be four to eight weeks, even sometimes 12 weeks before it becomes positive. The suggest is in the animal model they become positive sooner than the TST that has been definitively proven in humans.

DR. OSTROFF: The other question that I had is in how many of the studies where you looked at this have the operator in the type of actual people who would be running this assay? I mean, is it the type of test that I myself not being an experienced laboratorian could run with a high decree of reliability?

One of the concerns I have about the reproducibility study that you sited is that it looks like 95 percent of the samples were positive. I'm wondering if you have a group that is a little bit more variable than that how reproducible the results would be if, for instance, the proportion that was supposed to be negative was higher.

DR. ROTHEL: The FDA asked exactly that question. I must admit I was in Italy and didn't have time to get that data together to present to you. I

just pulled an old slide out. We tested 50 people that basically were negative. The vast majority were negative so the inverse of that population and submitted that to the FDA and the results were very much the same. I think it was .85. It was just nearly exactly the same. That was done at three different sites.

What was the first part of the question?

DR. OSTROFF: About who can -- I mean, how trained do you have to be to run this test?

DR. ROTHEL: On the 6,000 animals that I showed you for that study, that was done in an office in the middle of the Outback with no lab facilities. It's very robust. You can do it on a bench. You don't need any fancy equipment other than the ELISA reader.

It involves putting up 4 mil bloke into a pit and going one, two, three, four additions in a well. The kit comes with dropper bottles. You just put three drops of each antigen into each of the four units of blood and putting it in an incubator over night.

Then the ELISA. Yeah, you need to have some experience in a lab to perform an ELISA. I think anyone who ever worked in a pathology laboratory would

have no problems with it. It's a very simple ELISA. Again, it's controlled so if it doesn't work it comes out with an invalid result and must be repeated. It's a very rare event.

DR. GARDNER: Just a couple. This test depends on numbers and functions of T-cells. Can you give us some figures as to varying ranges of T-cell and what subsets are most important in listing this response?

DR. ROTHEL: I'm sure we're measuring both CD4 and CD8. Predominately we're measuring CD4 obviously because that's the more powerful QuantiFERON but we haven't actually done that analysis in trying to kill off the CD4 cells and see what the CD8s produce, you know, whole blood culture or magnetic bead separation. We were actually talking about that the other day.

As far as the absolute numbers you need, I think the data comes from the HIV population and that study Col. Carl Mason performed in Kenya with us looking at tea plantation workers. Of the 900 or so people HIV rate was about 16 percent. We had CD4 counts on all of them.

Basically if the CD4 count is greater than 200 the test works fine. Less than 200 it doesn't

work that well. What is surprising is we had one person with a CD4 count of six and we got a result out of them.

DR. GARDNER: Also you run a mycobacterium avian is tested but what about other non-tuberculous mycobacteria if you had a camsascii or something like that. What would you expect? Do you have any data with regard to other non-tuberculous mycobacteria?

DR. ROTHEL: We have various data from cattle where we experimentally infected with mycobacteria avian camsascii and inburbis in control animals obviously. Camsascii and avian animals responded predominately to mycobacteria avian PPD. I think camsascii, for example, was closer to mycobacteria avian in its antigenic content than it is to mycobacteria and tuberculosis. We've got a handful of patients, that's all, which holds up that trend.

DR. GARDNER: Then, finally, you gave us -- you said it was cost effective. You gave us the cost of skin testing but you didn't give us a cost for this test. It makes a difference as to whether it's used as a primary.

It seems to me this test as we heard today needs to be used as the primary, not the thing you do after you get a positive tuberculin skin test so as a

screener it's different than as a follow-up. What is the range you expect to get with this test?

DR. ROTHEL: The list price that we are currently selling it for in the U.S. is $10 a person. I think laboratory cost associated with running it would be maybe up to another $10 per person. Maybe if Ledco were running it they might be charging more than that. I think in a military setting it would be less than $10.

DR. GARDNER: Does that include the venupuncture costs?

DR. ROTHEL: No, it doesn't. The best study is the cost effectiveness study that was performed and submitted to JNB. It was performed by Renee Held from Johns Hopkins. From memory that demonstrated the tests were equivalent in price. The higher ranking the person being tested, the better off you were with QuantiFERON because it accounted for the time with the person being tested. I think it was some obscene amount for a general like $150 to perform a skin test.

DR. CLINE: Just curious. How long does it take for a QuantiFERON positive individual after treatment is initiated for it to become negative?

DR. ROTHEL: The answer is we don't know. With the TST, I think a person who has had TB and

completed treatment remains TST positive for the rest of their life. The suggestion is that QuantiFERON responses are going down with treatment but yet to be proven.

DR. CLINE: I just wonder if it might be useful to monitor response to therapy?

DR. ROTHEL: It would be lovely and we would love to see that answer but I think we've got some studies underway with the CDC and other collaborators to address that but we just don't know the answer at the moment. It's looking possible.

DR. OSTROFF: I have a practical question, and unfortunately I know most of the preventive medicine liaisons to the Board aren't on the line and aren't present. In practical terms given the 12-hour time frame in which the specimen has to be tested, I'm wondering if there's been thought that's been given -- Jeff, I'm sure you're still on the line -- as to how many different testing sites there would have to be given the huge variety of settings in which tuberculin skin testing has traditionally been done in the military. How many testing sites are there going to have to be where this test is run?

COL. GUNZENHAUSER: Well, I think if it was available -- this is Col. Gunzenhauser. I think if it

was available on a case-by-case basis some of the sites may determine that it would be preferable for them to use it. Theoretically there would be scores of places that could want to use it. From a practical point of view it might be a handful find it of great value.

DR. OSTROFF: I think one of the difficulties, at least from what I've heard in the presentations, is you can't be switching back and forth between tests. In other words, if you have some peripheral sites that for one reason or another can't meet that 12-hour turnaround time and would prefer to use skin testing, it sounds like those individuals then can't be tested using the QuantiFERON test for a period of approximately a year.

If they then move to some other location, particularly here stateside, that could be a real issue. I think if we were to suggest that this test is ready for primetime, for want of a better term, in terms of using it in the military, that there would have to be a significant commitment to making sure that it gets used as the preferred test.

I don't think that we could, you know, state an option where you could go with either one of them because of this particular problem unless I'm

misreading something. Maybe Jerry can comment on that as well.

COL. GARDNER: Just to give you a ballpark -- this is Col. Gardner -- there are 15 recruit training centers and there are 104 or 108 military treatment hospitals. Those are just some numbers you can think about.

DR. ROTHEL: Just a couple of comments. I think one situation where it wouldn't have any effect what you were just talking about is military recruits because they wouldn't have been tested previously. The other comment about testing. Yeah, that's a problem but the whole test doesn't need to be done at the one place.

You can perform the first part of a test and have the placement samples remain stable for two weeks or up to three months frozen at 4 degrees so you can send it to a central place and have the ELISA component of the test done.

DR. MAZUREK: And the only other comment I would make is that it's probably reasonable in those people that have had a negative skin test to rely on the first QuantiFERON test done less than 12 months away if it is negative. If it's positive, then you are probably going to want to confirm it with a skin

test.

DR. PATRICK: Question. Is your company the only company that has this right now? Is that right?

DR. ROTHEL: Yeah. We have the patent to the test until 2011, I think, in the U.S.

DR. PATRICK: And the patent is on the interferon dimension of this?

DR. ROTHEL: The patent we own covers whole blood incubation of measuring gamma interferon so it's generic technology.

DR. PATRICK: Are there competitors on the horizon? What is your scan of the business environment?

DR. ROTHEL: I'll be totally up front. The only competitor in the TB diagnostic world is a company in Oxford who got an ELI spot test that they're doing which I think we all understand, if you know anything about the ELI spot test, is probably about $150 test per person. It's never going to work. You can do about five or six people a day, perhaps one person. There's no competitor that we are aware of.

DR. PATRICK: Is this technology useful in testing other --

DR. ROTHEL: Yes, it is. We are a very new

company. We've only been in existence for two years but we have a number of other applications for the technology. Lyme disease is one we have done a fair bit of work on. It does work very well for Lyme disease. There's obviously a whole lot of other things.

Chlamydia or any situation where an antibody test is maybe not that beneficial but a CMR response is beneficial but we can't with the measure currently. Toxcio mycosis, for example, is another one. Yeah, there is a host of applications but being such a young company having limited funds, to be honest, we have to get TB working first so that's where we are concentrating our efforts.

DR. GARDNER: Just coming back to your issue, Steve. It seems to me one of the most positive areas to think about using this is at the time of people entering the military and you've got them in 100 or fewer places and you can build a laboratory capacity. We now recommend follow-up tuberculin assessment at what interval?

DR. OSTROFF: Well, it's -- you know, again, if we had all the preventive medicine liaisons that were here, they could comment on it but it's not variable for the service to survey.

DR. GARDNER: But it's a couple of years? At that point they are dispersed and they are less timely.

DR. OSTROFF: There are a number of strategies that are employed by the various services. There is interval testing that goes on and then there is post-deployment testing if they have been deployed or if they have been overseas to an area that is considered a higher risk of tuberculosis.

DR. GARDNER: I guess my point is at admission they are getting blood taken. It's just another test you do. They are concentrated and it's easy to do. After that it becomes more complicated, I think, with not as standardized and not as grouped. What you don't want to do, as you point out, is to begin with this test, then give them a skin test two years later, and then have to worry about the booster effect.

DR. OSTROFF: Or have a false/positive TST. For those who have been on the Board for some period of time and have listened to the various sagas that have gone on in the services with tuberculin skin testing, you know it's been fraught with difficulty, particularly with circumstances in which there have been significant numbers of false positives for one

reason or another.

DR. GARDNER: Which would have been considered boosters.

DR. OSTROFF: And it's usually a problem with the skin testing product itself. Certainly if Commander Ludwig was on the phone, for those of us who have listened to her presentations over the years, she's always got some outbreak that she's investigating which turns out to be due to false/positive skin tests.

DR. GARDNER: But this is going to be a decision that will not be a mix and match decision. We have to go one way or the other it seems to me.

DR. OSTROFF: Bill.

DR. BERG: Everyone is down to serious questions. I'm just curious. This is Bill Berg. You are young impoverished company. I'm just curious how much it cost you to buy and test all those cattle?

DR. ROTHEL: We were very lucky actually. The company we bought the technology from got out of human diagnostics performed it and it was paid for by the Australian government. I think all in all the bovine study cost over a million dollars Australian. Most of the meat ended up in McDonald's hamburger over here, I think.

DR. OSTROFF: Other comments? Let me just say in comparison to the presentation from a couple of years ago, I was the one that had written the previous recommendation from the Board. There has been a tremendous amount of progress, particularly the licensure is no mean task to get that through the FDA. You are to be congratulated for how much this has progressed.

DR. ROTHEL: Thank you.

DR. OSTROFF: Why don't we go ahead and take a much needed 10-minute break. When we return we will have an update from John Gravenstein on what's going on with the smallpox vaccination program.

(Whereupon, at 3:23 p.m. off the record to Executive Session. Reconvene 8:00 a.m. March 19, 2003 in public session.)